IN THE UNITED STATES DISTRICT COURT

FOR THE EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA	**:**	
v.	**:**	**CRIMINAL NO. 21-136**
MURTY VEPURI **ASHVIN PANCHAL** **KVK-TECH, INC.**	**:** **:**	

UNITED STATES' OMNIBUS RESPONSE TO DEFENDANTS' PRETRIAL MOTIONS

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INTRODUCTION

The United States of America, by its counsel, Jennifer Arbittier Williams, United States Attorney for the Eastern District of Pennsylvania, and M. Beth Leahy, Patrick J. Murray, and Ronald A. Sarachan, Assistant United States Attorneys for the District, and Ross Goldstein and Alisha Crovetto, Trial Attorneys for the Consumer Protection Branch, U.S. Department of Justice, files this Omnibus Response to the defendants' pretrial motions seeking to (i) dismiss the Superseding Indictment on premature, and factually inaccurate, evidentiary challenges, ECF 96-1; (ii) dismiss as time-barred charges that are properly alleged in the indictment as being within the statute of limitations, ECF 94 and 102; (iii) strike entirely relevant statements from the indictment which, although true, the defendants complain put them in a bad light, ECF 93 and 103; (iv) obtain secret grand jury material without a proper basis, ECF 105; and (v) obtain the premature or improper disclosure of materials, ECF 98, 99, 100, 101.[1]

This tsunami of meritless motions appears to have been crafted to confuse the facts, misapply the law, and ultimately to avoid trial on the merits. For the reasons set forth below, the government respectfully submits that the defendants' motions should be denied in their entirety.

[1] The Court granted the defendants' requests for joinder of these motions. ECF 95, 97, 104.

BACKGROUND

Defendant KVK-TECH, Inc. ("KVK") is a generic drug manufacturer located in Newtown, Pennsylvania. Although his name does not appear on any ownership documents, defendant Murty Vepuri ("Vepuri") owns and operates KVK and its affiliate companies. Prior to KVK, Vepuri owned Able Labs ("Able"), a New Jersey-based generic manufacturer which the FDA cited for severe manufacturing deficiencies. Eventually, the FDA obtained an injunction to stop Able from shipping adulterated and potentially dangerous drugs. As part of a negotiated settlement with the FDA, Vepuri agreed to refrain from exercising any authority over operations at Able and that he would not be an officer, director, employee, or an otherwise responsible official of any business entity engaged in the manufacture, processing, packing, or holding of drugs.

When Vepuri formed KVK in 2003, he caused the ownership of the company to be placed in trusts for the benefit of each of his three adult children, to conceal his true role in the business. Vepuri repeatedly held himself out to the FDA as a part-time consultant and/or advisor when, in reality, he directed KVK's day-to-day operations and closely controlled the trusts that owned the company. Vepuri made all key business decisions for KVK, including decisions related to drug composition, regulatory requirements, manufacturing quality, purity, and potency, and the purchase of Active Pharmaceutical Ingredient ("API") to manufacture drugs.

In or about January 2005, Vepuri hired defendant Ashvin Panchal ("Panchal") as KVK's Director of Quality Assurance ("QA"). At the time he was recruited, Panchal was a citizen of India. KVK sponsored Panchal for an H-1B Visa, which allowed nonimmigrant aliens to enter or remain in the United States for temporary work in a specialty occupation. To stay in the United States on an H-1B Visa, Panchal was required to remain employed in good standing with

KVK. With the assistance of Panchal and others, Vepuri cut corners and circumvented regulatory requirements that were in place to ensure that KVK manufactured and distributed prescription drugs that were safe and effective.

In 2008, KVK obtained FDA approval to market one of its first drugs, the sedative Hydroxyzine Hydrochloride ("Hydroxyzine"). The API in Hydroxyzine was hydroxyzine hydrochloride ("HCL API"). The FDA approved KVK's Abbreviated New Drug Application ("ANDA") for Hydroxyzine, permitting it to manufacture Hydroxyzine with HCL API sourced from two FDA-approved suppliers—UCB Pharma, S.A. ("UCB") and Cosma, S.p.A. ("Cosma")—at FDA-approved manufacturing sites in Belgium and Italy, respectively. UCB stopped manufacturing HCL API after an explosion at its Belgium facility, and, in or about 2010, at Vepuri's direction, KVK obtained HCL API through UCB that was manufactured by an unapproved contractor and facility, Dr. Reddy's Laboratories ("DRL") in Morelos, Mexico. Panchal, in his role as KVK's QA Director, approved the use of the unapproved HCL API to manufacture and sell Hydroxyzine. According to FDA regulations, the ANDA holder, in this case KVK, must notify the FDA of changes in the conditions approved in the ANDA and, in most instances, wait for the FDA's approval before distributing the drug. 21 C.F.R. § 314.70. If a distributed drug differed in a condition established in an approved ANDA, it was not the approved drug, and the FDA could not ensure that the drug was safe and effective for its intended use. KVK concealed from the FDA that it manufactured Hydroxyzine with HCL API from an unapproved source that was not included in the ANDA.

On or about April 11, 2011, KVK began distributing Hydroxyzine that it manufactured with the unapproved HCL API from DRL Mexico. On or about June 3, 2011, the FDA issued a

Warning Letter[2] to DRL in Mexico arising from significant violations of current Good Manufacturing Practices ("cGMP")[3] identified during an FDA inspection of the Morelos facility conducted in or about November 2010. The FDA warned that API manufactured by DRL Mexico was deemed "adulterated."

On or about June 20, 2011, Vepuri advised Panchal that DRL in Mexico had received an FDA Warning Letter in connection with the significant violations at the Morelos facility. FDA regulations required KVK to notify the FDA about any significant changes that had the potential to impact a marketed drug. 21 C.F.R. § 314.81. Notwithstanding the FDA's clear position that API from DRL in Mexico was adulterated, KVK continued to conceal from the FDA that it was distributing Hydroxyzine manufactured with HCL API from DRL in Mexico.

In addition to the Warning Letter, on or about July 7, 2011, the FDA issued an import alert[4] for API manufactured by DRL in Mexico due to the significance of the violations the FDA uncovered. The import alert authorized the detention of any API manufactured by DRL in Mexico and imported to the United States, and it remained in effect until on or about July 12, 2012. During that time, the FDA was unaware that KVK had imported HCL API manufactured

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[2] FDA Warning Letters are "the agency's principal means of achieving prompt voluntary compliance with the Federal Food, Drug, and Cosmetic Act" and are "based on the expectation that most individuals and firms will voluntarily comply with the law." FDA, Regulatory Procedures Manual § 4-1-1 (2021). The FDA issues Warning Letters only for "significant violations" that "may lead to enforcement action if not promptly and adequately corrected." *Id.*

[3] cGMPs were the generally recognized minimum industry standards to assure the identity, strength, quality, and purity of drug products.

[4] Import alerts identify products and/or shippers that are in violation of the Federal Food, Drug, and Cosmetic Act (the "FDCA") and permit the agency to detain a product without physically examining it at the time of entry in order to prevent the problem product from being distributed in the United States. *See Import Alerts* (http://www.fda.gov/industry/actions-enforcement/import-alerts).

by DRL in Mexico, and that KVK was distributing Hydroxyzine tablets containing the unapproved API from DRL in Mexico.

In or about May 2013, still without providing any notice to FDA, Vepuri authorized an additional purchase of HCL API manufactured by DRL in Mexico. On or about June 4, 2013, Vepuri's additional purchase arrived in Philadelphia International Airport in the form of 19 drums of imported HCL API manufactured by DRL in Mexico. The drum labels showed Mexico as the country of origin. United States Customs ("Customs") detained the API and refused its entry. Customs notified the FDA that KVK had attempted to import an API from an unapproved foreign source.

To create the false impression that DRL in Mexico was a new supplier of HCL API for which KVK intended to seek regulatory approval, Panchal quickly submitted a Change Being Effected in 30 Days Notice ("CBE-30") with the FDA. A CBE-30 is a vehicle used to notify the FDA of a *prospective* change to an approved drug that a manufacturer expects to be implemented within 30 days. 21 C.F.R. § 314.70(c). Panchal asserted in the CBE-30 that KVK would await approval to use the API before beginning process validation and stability studies. Panchal concealed from the FDA that KVK had already distributed, and was continuing to distribute, Hydroxyzine made with HCL API from DRL in Mexico, which was the same source of API that the FDA had refused entry into the United States. The FDA rejected the CBE-30 because KVK's API site change was a major change for which the ANDA holder, KVK, was required to file a comprehensive Prior Approval Supplement for the FDA's evaluation and approval.

Beginning on or about November 14, 2013 until on or about December 9, 2013, the FDA inspected KVK's facilities. As part of the inspection, the FDA reviewed KVK's raw materials acceptance process. The FDA inspectors specifically inquired about KVK's procedures to

prevent API from an unapproved source, such as the 19 drums of HCL API from DRL in Mexico, being used to manufacture its drugs. Once again, Panchal concealed from the FDA that KVK had been distributing Hydroxyzine containing the same API from DRL in Mexico since 2011.

During the inspection, the FDA observed photos of raw materials labels in KVK's files. Some of the photos showed drums labeled "Made in Mexico" and markings in Spanish on various areas of the containers. The labels were from earlier shipments of HCL API from DRL in Mexico. The FDA inspectors uncovered that KVK had previously distributed approximately 62 lots of Hydroxyzine manufactured with HCL API from DRL in Mexico. From on or about April 12, 2011 through on or about October 21, 2013, KVK distributed at least 368,311 bottles of Hydroxyzine tablets made with HCL API manufactured by DRL in Mexico.

In their communications with the FDA inspectors, Vepuri, Panchal, and KVK falsely denied knowing that the company had distributed Hydroxyzine with HCL API from Mexico. Instead, they blamed a former employee for making an "inappropriate regulatory evaluation for the site change." Due to the seriousness of the violations uncovered at KVK, the FDA inspectors recommended that the FDA's Compliance Branch issue a Warning Letter. Instead, the Compliance Branch decided to hold a regulatory meeting with KVK representatives in order to further explore the cause of the issues identified during the inspection, the most important of which was KVK's use of unapproved HCL API. This regulatory meeting was held on or about June 24, 2014. Vepuri, Panchal, and other KVK representatives continued to advance the false narrative that a mistake by an incompetent former employee had caused KVK to inadvertently manufacture and distribute Hydroxyzine with unapproved HCL API.

As Vepuri and Panchal well knew, the *intentional* importation and use of unapproved API would raise serious concerns within the FDA about KVK's other marketed drugs and its pending ANDAs. Accordingly, during a follow-up inspection by the FDA on or about November 17, 2014 through on or about December 11, 2014, Panchal continued to take action and make statements to convince FDA of the false narrative that KVK had unknowingly distributed the unapproved Hydroxyzine. On or about December 11, 2014, Panchal provided a document to the FDA titled Manufacturing Deviations and Investigations Report (the "MDI report"), which was purportedly a comprehensive report, signed by Panchal, detailing KVK's investigation and conclusions related to the API manufactured by DRL in Mexico. The MDI contained false and misleading information, including that it was "not clear why the manufacturer UCB Pharma S.A. shipped API manufactured in Mexico." As Panchal knew, Vepuri had specifically authorized the purchase of the HCL API manufactured by DRL in Mexico. The lead FDA inspector discussed the MDI report with Panchal and other KVK representatives at the inspection closing meeting held on or about December 11, 2014. Panchal stood by the false narrative established in the MDI report. After the FDA released a final Establishment Inspection Report ("EIR") for the follow up inspection on or about March 2, 2015, Vepuri, Panchal, and KVK, knowing the EIR was substantially false based on information that they had provided, failed to notify the FDA of the falsehoods in furtherance of their scheme to defraud the FDA.

As alleged, under Vepuri's control, KVK ignored those regulatory requirements that had the potential to slow the manufacture, distribution, and sales of its drugs. When inspectors identified violations, Vepuri and Panchal provided false explanations to the FDA to avoid further FDA scrutiny and having to tighten KVK's operations and bring them into compliance. Often,

Vepuri and Panchal falsely attributed regulatory failures to a mistake or misunderstanding, and KVK would falsely assure the FDA that violations had been addressed when, in fact, and as they well knew, no corrective and preventative actions were taken. The objects of the conspiracy were to defraud, mislead, and defeat the lawful functions of the FDA by knowingly and willfully making materially false, fictitious, and fraudulent statements and representations, and falsifying and concealing material facts in a matter within the jurisdiction of the FDA, including the unapproved distribution of unapproved Hydroxyzine. Contrary to the defendants' assertions, the charged conduct does not arise from a mere "paperwork violation." ECF 96-1 at 26.[5]

As a result of the significant cGMP violations uncovered and KVK's deceptive conduct related to the unapproved API, on or about July 14, 2014, the FDA Philadelphia District Office

[5] The defendants present a misleading narrative about the charged conduct. They proclaim that "there was not then, nor has there even been, any allegation that the API was unsafe or ineffective." ECF 96-1 at 7. The fact that KVK recalled the drugs made with API from DRL in Mexico belies any claim that there were no such concerns. Further, by the time the scheme was uncovered, the API obtained in 2011 had been fully consumed and was thus unavailable to the FDA for evaluation. Likewise, the defendants' claim that "were this case to proceed to trial, KVK would show that FDA's own testing confirmed that the material from DRL was safe, effective and fully interchangeable with the material made in-house by the Belgian manufacturer" is unavailing. Defendants' reference to test results is misleading, as testing was performed on the DRL in Mexico API seized by U.S. Customs in June 2013, not the unapproved API obtained by KVK in 2011. The 2013 API was manufactured *after* the Morelos facility was remediated and the FDA Warning Letter and Import Alert were lifted. The FDA did not test the HCL API that KVK had obtained in 2011, so there is no basis on which to claim that the FDA considered API manufactured in Belgium and Mexico to be equivalent. Moreover, testing alone is not adequate to ensure drug quality. Drugs must be produced in adherence with cGMP, which is a comprehensive system of conditions and practices to ensure that quality is built into the design and manufacturing process at every step. Without adherence to cGMP, a manufacturer cannot assure that the drugs it produces are safe and effective. The HCL API that KVK used to manufacture and distribute hydroxyzine in or about 2011 through in or about 2013 was not produced under cGMP and was therefore adulterated as a matter of law. *See* 21 U.S.C. § 351(a)(2)(B) ("A drug or device shall be deemed to be adulterated . . . if it is a drug and methods used in, or the facilities or controls used for, its manufacture, processing, packing or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice . . . ."). Thus, the defendants cannot truthfully represent that the API at issue from DRL in Mexico was equivalent to the UCB material manufactured in Belgium.

(Compliance Branch) referred this matter for criminal investigation to the Washington, DC Headquarters of the FDA Office of Criminal Investigations.

On or about December 23, 2016, the Office of International Affairs of the Department of Justice made an official legal assistance request through a Mutual Legal Assistance Treaty ("MLAT") to obtain evidence from UCB, a Belgian entity, through the Central Authority of Belgium. On or about February 27, 2017, pursuant to 18 U.S.C. § 3292 (Suspension of Limitations to Obtain Foreign Evidence), the Honorable United States District Judge Cynthia M. Rufe granted the government's *ex parte* application for suspension of the running of the statute of limitations in connection with the investigation of Vepuri, Panchal, KVK, and others for the following specified offenses: conspiracy to commit an offense and/or to impair and impede the lawful functioning of an agency of the United States, in violation of 18 U.S.C. § 371; smuggling of goods into the United States, in violation of 18 U.S.C. § 545; making false statements, in violation of 18 U.S.C. § 1001; mail fraud, in violation of 18 U.S.C. § 1341; wire fraud, in violation of 18 U.S.C. § 1343; and introduction of adulterated drug product into interstate commerce, in violation of 21 U.S.C. § 331(a). UCB's final production was made on or about January 8, 2018. Under 18 U.S.C. § 3292, the MLAT extended the statute of limitations for the specified offenses by six months.

During the investigation, the parties entered into multiple tolling agreements beginning on May 23, 2019, September 9, 2019, and June 8, 2020, for KVK, Vepuri,[6] and Panchal

[6] On April 5, 2021, the government filed an information charging Vepuri with one count of distributing an unapproved new drug, in violation of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 331(d), 355(a), and 333(a)(1), pursuant to a negotiated, written plea agreement signed by the defendant and his former counsel, Ronald Levine, Esquire, on March 22, 2021. The charge was in connection with the defendant's role as the *de facto* owner and operator of KVK. On May 17, 2021, Mr. Levine notified the Court that Vepuri had reneged on the

respectively. The last tolling agreements executed by each defendant had an expiration date of June 14, 2021.

On June 10, 2021, a grand jury returned a two-count superseding indictment (the "Superseding Indictment" or "indictment") charging defendants Vepuri, Panchal, and KVK with one count of conspiracy to defraud the United States and to commit offenses against the United States, in violation of 18 U.S.C. § 371. KVK was also charged with one count of mail fraud, in violation of 18 U.S.C. § 1341, for selling unapproved drugs to unknowing customers who were falsely assured by KVK that its drugs conformed with FDA regulations.[7]

ARGUMENT

I. DEFENDANTS' MOTIONS TO DISMISS THE SUPERSEDING INDICTMENT AS A MATTER OF LAW SHOULD BE DENIED

The defendants ask this Court to dismiss the Superseding Indictment as a matter of law on three bases: 1) KVK did not commit any underlying regulatory violations; 2) KVK cannot be charged with conspiring with its own agents; and 3) the mail fraud charge is fatally defective because KVK did not conceal any material facts. ECF 96-1. These arguments are baseless and have no bearing on the sufficiency of an indictment.

A federal indictment need include only "a plain, concise, and definite written statement of the essential facts constituting the offense charged" and "the official or customary citation of

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agreement and would not plead guilty. Because Mr. Levine expressed interest in resurrecting negotiations with the government, the parties executed a tolling agreement suspending the statute of limitations from the date on which Vepuri reneged on the agreement until June 14, 2021.

[7] On or about July 14, 2021, the government executed search warrants at KVK's facilities authorized by the Honorable U.S. Magistrate Judge Elizabeth T. Hey. The government established probable cause that KVK was engaged in ongoing violations of the FDCA and abuse of H-1B visas. The government seeks to bring additional charges related to these violations in a second superseding indictment.

the statute, rule, regulation, or other provision of law that the defendant is alleged to have violated." Fed. R. Crim. P. 7(c)(1). An indictment is sufficient under Rule 7 if it:

> (1) contains the elements of the offense intended to be charged, (2) sufficiently apprises the defendant of what he must be prepared to meet, and (3) allows the defendant to show with accuracy to what extent he may plead a former acquittal or conviction in the event of a subsequent prosecution.

United States v. Kemp, 500 F.3d 257, 280 (3d Cir. 2007) (quoting *United States v. Vitillo*, 490 F.3d 314 (3d Cir. 2007)). "[N]o greater specificity than the statutory language is required so long as there is sufficient factual orientation to permit the defendant to prepare his defense and to invoke double jeopardy in the event of a subsequent prosecution." *Id.* (quoting *United States v. Rankin*, 870 F.2d 109, 112 (3d Cir. 1989)); *see also United States v. Moyer*, 674 F. 3d 192, 203 (3d Cir. 2012).

Rule 12 permits a defendant to move to dismiss an indictment for failure to state an offense. Fed. R. Crim. P. 12(b)(3). The defendants must show that the Superseding Indictment, on its face, fails to charge an essential element of the crime. *United States v. Stock*, 728 F.3d 287, 292 (3d Cir. 2013).

In this case, the four corners of the Superseding Indictment show that it charges the elements of the offenses and meets the requirements of Federal Rule of Criminal Procedure 7(c)(1). The defendants have not claimed otherwise. To sidestep their failure to meet the threshold requirement to support dismissing an indicted charge, the defendants go beyond the face of the Superseding Indictment. They allege that "KVK did not violate any actual regulatory requirements" and "without this regulatory foundation, the government cannot *establish* the essential elements of each offense," ECF 96-1 at 15 (emphasis added), and cannot "*establish* any alleged object of the conspiracy count, or the scheme to defraud element of the mail fraud count," *id.* at 16 (emphasis added). Whether the government can *establish* the

elements and/or the object of the conspiracy at trial is not a basis for dismissing an indictment. *United States v. DeLaurentis*, 230 F.3d 659, 660 (3d Cir. 2000) (citations omitted) ("[A] pretrial motion to dismiss an indictment is not a permissible vehicle for addressing the sufficiency of the government's evidence"). Further, "[i]n evaluating a Rule 12 motion to dismiss, a district court must accept as true the factual allegations set forth in the indictment" and "determin[e] whether, assuming all of those facts as true, a jury could find that the defendant committed the offense for which he was charged." *United States v. Huet*, 665 F.3d 588, 595–96 (3d Cir. 2012). An indictment should be tested solely on the basis of the allegations made on its face, and such allegations are to be taken as true. *United States v. Todd*, 446 F.3d 1062, 1068 (10th Cir. 2006) ("On a motion to dismiss an indictment, the question is not whether the government has presented sufficient evidence to support the charge, but solely whether the allegations in the indictment, if true, are sufficient to establish a violation of the charged offense.").

A. <u>The Regulatory Violations Alleged Do Exist</u>

According to the defendants, Counts One and Two of the Superseding Indictment rest on a flawed legal premise that KVK violated FDA regulations. ECF 96-1 at 15. They allege that the charged conspiracy depends on "violations that do not exist" and, even if KVK did violate regulations, the violations did not result in Hydroxyzine becoming an unapproved drug. *Id.* The defendants' arguments ignore the language of the FDA regulations, rely on purported facts that

are not alleged in the indictment, take excerpts of regulations and guidance out of context, and would produce absurd results.[8]

1. KVK Was Required to Notify the FDA About the API from DRL in Mexico and Obtain FDA Approval

The indictment is based on the unremarkable fact that when a manufacturer and distributor of a generic drug in the United States begins using an active ingredient for the drug—the "API"—manufactured at a different facility, it must inform the FDA so that the FDA can ensure the new facility meets necessary quality requirements. In this regard, the Federal Food, Drug, and Cosmetic Act (the "FDCA") requires that an application for a new drug contain a full description of the facilities, methods, and controls used for the manufacturing, processing, and packaging of the drug. 21 U.S.C. § 355(b)(1)(A)(iv), (j)(2)(A)(vi). As alleged in the indictment, KVK in its ANDAs filed with the FDA for Hydroxyzine specifically represented that the drugs would be manufactured by UCB at its facility in Braine-l'Allued, Belgium. ECF 4 at 4-5, ¶ 12. The FDCA further required that for a change in manufacturing, the applicant holder, in this case KVK, must submit a supplemental application to FDA or otherwise report the change to the FDA, depending on the seriousness of the change. 21 U.S.C. § 356a. FDA regulations required the applicant to notify the FDA about any change in any condition in an approved ANDA and describe the change fully. 21 C.F.R. § 314.70(a). The form of the required communication to the FDA varied depending on whether the change was major, moderate, or minor. 21 C.F.R.

[8] Moreover, the defendants ignore the fact that they are charged with a multi-object conspiracy. A guilty verdict in a multi-object conspiracy will be upheld if the evidence is sufficient to support a conviction based on any of the alleged objects. *See Griffin v. United States*, 502 U.S. 46, 56-60 (1991). Here, even if KVK did not commit any underlying regulatory violations, they could still be found guilty of Count One if the jury found that they conspired to defraud the FDA or to make false statements.

§ 314.70(b). Although as the applicant and holder of the ANDA, KVK was required by statute and regulation to notify the FDA of the change in API manufacturing facility to DRL in Mexico, the defendants failed to communicate the change to the FDA in any form and instead concealed their use of the Mexican facility, until they were caught red-handed. *See, e.g.*, ECF 4 at 9-13 (Overt Act Paragraphs 8 through 12 and 16).

Further, the indictment alleges facts that establish that the manufacturing change to the Mexico DRL facility was a major change under 21 C.F.R. § 314.70(b), requiring KVK to file a supplement to its ANDA and obtain FDA approval **before** using API manufactured at that facility. Pursuant to 21 C.F.R. § 314.70(b), a change in the "production process, quality controls, equipment or facilities that has a substantial potential to have an adverse effect on the identity, strength, quality, purity, or potency of the drug product" is a major change triggering the need to submit a supplemental application to the FDA. As alleged in the indictment, the change to DRL's Mexico facility had more than a "substantial potential" for an adverse effect of the drug product; it had an *actual* adverse effect, as evidenced by the fact that the FDA found that API manufactured at DRL in Mexico was adulterated and issued a Warning Letter and import alert. ECF 4 ¶ 15. Moreover, the fact that the change to DRL in Mexico was a major change under the regulations was also fully supported by the applicable FDA guidance interpreting these regulations for manufacturers. Under that guidance, it was a major change to "move to a different manufacturing site . . . when the new manufacturing site does not have a satisfactory CGMP inspection for the type of operation being moved." FDA, *Guidance for Industry, Changes to an Approved NDA or ANDA* (the "FDA Guidance") at 9.[9] Rather than an inspection

[9] "Guidance documents do not establish legally enforceable rights or responsibilities. They do not legally bind the public or FDA." 21 C.F.R. § 10.115(d).

with satisfactory results, the FDA found that API manufactured at DRL in Mexico was adulterated. ECF 4 at 5-6, ¶ 15. As further alleged in the indictment, defendants Vepuri's and Panchal's response to the Warning Letter was to buy and use additional API from DRL in Mexico without notifying the FDA. *Id.* at 9-10 (Overt Act Paragraphs 7 through 10).

Significantly, the defendants' conduct reflected their understanding of the notification requirement to the FDA of any new HCL API manufacturing facility. For example, in 2008 when KVK added a new manufacturing site for HCL API located in Italy, the FDA required KVK to file a Prior Approval Supplement to obtain agency approval prior to distributing Hydroxyzine made with the API from Italy, consistent with a major change. The defendants submitted the required Prior Approval Supplement. *Id.* at 5, ¶ 13. Similarly, in June 2013, when Customs caught the defendants unlawfully importing HCL API from DRL in Mexico, the defendants did not argue that they were not required to notify FDA of the change; instead, defendant Panchal quickly responded by filing a CBE-30 to notify the FDA and explain, albeit after the fact, the change in "manufacturing site from Braine-Alleu [sic] to Mexico." *Id.* at 10-11 (Overt Act Paragraphs 10 through 12).[10] On a motion to dismiss, the Court must accept all of these allegations in the indictment as true. *Huet*, 665 F.3d at 595-96.

In light of these statutory and regulatory requirements, reinforced by the defendants' alleged conduct during the conspiracy affirming their understanding of the requirements, the defendants' insistence now that they did not violate any regulations is entirely without merit. Nonetheless, in an effort to circumvent the regulatory requirements, the defendants now claim that KVK was not required to notify the FDA or to obtain FDA approval to manufacture

[10] Notably, the FDA rejected the CBE-30 because KVK's API site change was a major change for which KVK was required to file a comprehensive Prior Approval Supplement for the FDA's evaluation and approval.

Hydroxyzine with API sourced from DRL in Mexico because "DRL produced material according to UCB's methods and specifications, and, as noted, UCB remained responsible for the final API," and thus the switch did not change any conditions in the ANDA. ECF 96-1 at 17.

The defendants' argument would dangerously subvert FDA regulation. According to their argument, once the FDA had approved KVK's use of UCB-manufactured HCL API at UCB's Belgium facility, UCB would be free to switch to any manufacturing facility run by any other company anywhere in the world, and KVK would not be required to even notify the FDA of the change. As long as UCB remained as the middleman, any change in manufacturing facilities of API used by KVK would be unregulated. Such a perverse paradigm would make evasion of FDA regulation by creating corporate middlemen very simple indeed. There is nothing in the FDA regulations that permit this.

The defendants acknowledge that a change in API manufacturer is a reportable event pursuant to 21 C.F.R. §314.70(a)(1)(i),[11] however, they claim that UCB remained the API manufacturer and not DRL because, even though UCB subcontracted manufacturing to DRL in Mexico, UCB tested the DRL API before releasing it to KVK. ECF 96-1 at 18. This argument fails on a motion to dismiss because it relies on purported facts that are not alleged in the indictment; at most, it would raise a factual issue. More fundamentally, the argument is flat wrong. The fact that UCB continued to perform some functions that fall within FDA's definition of "manufacture"[12] does not mean that DRL was not *also* acting as a manufacturer. In fact,

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[11] 21 C.F.R. § 314.70(a)(1)(i), *Changes to an approved NDA* ("Except as provided in paragraph (a)(1)(ii) of this section, the applicant must notify FDA about each change in each condition established in an approved NDA").

[12] 21 C.F.R. § 207.1 defines manufacture to include manipulation, sampling, testing, or control procedures applied to the final product or to any part of the process, including for example, analytical testing of drugs for another registered establishment's drug.

KVK's own supplement for Hydroxyzine submitted on July 11, 2014 described the reason for the submission was to notify FDA of a "change in drug substance manufacturing site." In addition, UCB's "Process Description" also references DRL as "the new manufacturing site." KVK's amended Prior Approval Supplement filed on July 17, 2014 also describes DRL as performing "manufacture of drug substance" and UCB as performing "testing and release of Drug Substance."

The defendants also allege that "DRL produced material according to UCB's methods and specifications" and therefore it did not violate a condition established in the ANDA. ECF 96-1 at 17. Again, the defendants seek to insert factual allegations into the indictment, but that is improper on a motion to dismiss. Any factual issues such as this will be resolved at trial. In any case, the defendants' assertion is belied by KVK's own documents. On or about July 11, 2014, KVK filed a supplement after the recall of Hydroxyzine to obtain approval to use API from DRL in Mexico. The "Process Description" in this filing explained that "hiring of a subcontractor implicated technological updates to adapt the process to the new manufacturing site," and added: "In addition, current regulatory requirements associated with the filing of the new manufacturer also involve an update of drug substance specifications meaning that some limits have been tightened and new specifications implemented." The Process Description then listed some of the manufacturing changes resulting from the switch to DRL in Mexico:

- Starting materials, reagents, solvents, intermediates and active substance specifications have been revisited.
- Analytical methods similar to the methods mentioned in the original application are used to control the starting materials, reagents and solvents but the tests will be performed according to the procedures of the new manufacturer of the *active* substance.
- Analytical methods for the drug substance have been updated taking into account current scientific knowledge and current guidelines.
- Re-validation of analytical methods has been performed as appropriate.

This filing, which described DRL as the "manufacturing site," demonstrates clearly that KVK's use of API from DRL in Mexico resulted in changes to the API manufacturing process that required FDA evaluation and approval.

KVK argues further that the FDA's Guidance shows that DRL was not the manufacturer because this guidance refers to manufacturing sites as "includ[ing] those owned by the applicant or contract used by the applicant." This argument misreads the Guidance and ignores the regulations. In fact, the regulations broadly define a "manufacturer" as "a person who owns or operates an establishment that manufactures a drug," and explains that this "includes, but is not limited to, control laboratories, contract laboratories, contract manufacturers, contract packers, contract labelers, and other entities that manufacture a drug." 21 C.F.R. § 207.1. Furthermore, the regulations define "manufacture" very broadly as "each step in the manufacture, preparation, propagation, compounding, or processing of a drug[, including] the making by chemical, physical, biological, or other procedures or manipulations of a drug." *Id.* There is no question under these definitions that DRL "manufactured" HCL APL and that KVK was required to notify FDA of the move to this "manufacturer."

Moreover, the facts of this case fit this language in the FDA regulations and the Guidance. As alleged in the indictment, KVK *used* HCL API from the DRL Mexico site and *contracted* for it through UCB. There is absolutely nothing in the FDCA or its implementing regulations suggesting that the details of the structure of the contractual arrangements, including use of sub-contractors, relieve the applicant holder of its responsibilities to assess the significance of changes in manufacturing and notify the FDA of them. Under the defendants' interpretation, the regulations would permit KVK to knowingly use API manufactured by any contract manufacturer engaged by its approved API supplier. This would essentially circumvent

the drug approval process. The abuses that would arise from such an absurd interpretation are obvious and would create predicable lapses in the quality of prescription drugs distributed in the United States. The defendants' efforts at legal legerdemain to create artificial distinctions not contained in either the applicable law or agency guidance should be rejected.

Finally, the defendants further allege that even if KVK was required to notify the FDA about the change in the source of its API, the FDA received notice when UCB amended its Drug Master File ("DMF"). ECF 96-1 at 19. This ignores the fundamental premise underlying the statute and the regulations, which clearly put the burden squarely on the applicant of the approved ANDA to notify the FDA of changes to its ANDA. *See* 21 U.S.C. § 356a; 21 C.F.R. § 314.97; *see also* 21 C.F.R. § 314.420 (regulations on drug master files). For that reason, the "FDA ordinarily neither independently reviews drug master files nor approves or disapproves submissions to a drug master file. Instead, the agency customarily reviews the information only in the context of an application under [21 C.F.R. § 314]." 21 C.F.R. § 314.420(a). "An investigational new drug application or an application, abbreviated application, amendment, or supplement may incorporate by reference all or part of the contents of any drug master file in support of the submission if the [drug master file] holder authorizes the incorporation in writing." 21 C.F.R. § 314.420(b).

These statutes and regulations make it clear that the burden is on the ANDA holder, in this case KVK, to supplement its application for changed conditions, and here, KVK failed to do this. .[13]

[13] As the facts at trial will show, KVK incorporated the UCB DMF with respect to Hydroxyzine when it filed its ANDA for Hydroxyzine. At that time the DMF identified Belgium as the manufacturing site. While UCB subsequently amended its DMF to provide for the manufacture of HCL at DRL in Mexico, this amendment to the DMF was not incorporated into the ANDA until KVK filed its Prior Approval Supplement in or about July 2014. Further,

2. The Relevant FDA Regulations Are Not Vague

The defendants also argue that the FDA's regulatory scheme is too vague and unclear to serve as a basis for criminal liability. ECF 96-1 at 19. The void-for-vagueness doctrine reflects the fundamental principle that, in order to comply with the requirements of due process, a statute must give fair warning of the conduct that it prohibits. *See Bouie v. City of Columbia*, 378 U.S. 347, 351 (1964) ("We have recognized . . . that a statute which either forbids or requires the doing of an act in terms so vague that men of common intelligence must necessarily guess at its meaning and differ as to its application violates the first essential of due process of law . . . ." (internal quotation marks and citation omitted)). A statute is unconstitutionally vague under the Due Process Clause if it "(1) 'fails to provide people of ordinary intelligence a reasonable opportunity to understand what conduct it prohibits'; or (2) 'authorizes or even encourages arbitrary and discriminatory enforcement.'" *United States v. Stevens*, 533 F.3d 218, 249 (3d Cir.2008), *aff'd*, 559 U.S. 460 (2010) (quoting *Hill v. Colorado*, 530 U.S. 703, 732 (2000)). "In criminal cases, because vagueness attacks are based on lack of notice, they may be overcome in any specific case where reasonable persons would know their conduct puts [them] at risk of punishment under the statute." *United States v. Moyer*, 674 F.3d 192, 211 (3d Cir. 2012) (internal quotation marks and citation omitted). Where, as here, a statute does not involve rights guaranteed by the First Amendment, [courts] examine whether it is vague "as-applied to the

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evidence obtained during the investigation, of which the defendants are aware, proves that KVK knew that it had to notify the FDA of the change and that UCB's update to its DMF was not sufficient. In addition, UCB's DMF, which was eventually incorporated by cross-reference, *did* change when it was amended to include DRL as a new manufacturing site. The method of manufacturing and the established specifications for the API also changed, per UCB's amendment to the DMF. Although KVK appears to argue that these changes to the DMF were somehow automatically incorporated into the ANDA, obviating any need for KVK to seek FDA approval, that is not the case.

affected party." *United States v. Fullmer*, 584 F.3d 132, 152 (3d Cir. 2009); *see also United States v. Mazurie*, 419 U.S. 544, 550 (1975) ("It is well established that vagueness challenges to statutes which do not involve First Amendment freedoms must be examined in the light of the facts of the case at hand." (citation omitted)).

Because this case does not involve a First Amendment challenge, the appropriate standard is whether these requirements are impermissibly vague *as applied* in this case. The essence of the defendants' argument is that the FDA regulations are vague as to whether the manufacturing change was major, moderate, or minor, each category requiring a different regulatory response. A fundamental flaw in this argument is that the manufacturing change required some form of notice to the FDA, regardless of its category, *see* 21 C.F.R. § 314.70, and the defendants gave no notice. Rather, the defendants (1) concealed the change until they were caught red-handed importing HCL API from Mexico, and then they (2) concealed from the FDA that they had already been importing the Mexican API and used it to distribute Hydroxyzine, and then when inspectors uncovered that lie, they (3) tried to blame it on inadvertent error by a former employee, and hide that it was caused by Vepuri, the supposed consultant.

Moreover, the FDA regulations are not vague with respect to the changes at issue in this case being a condition of the ANDA and requiring a Prior Approval Supplement (before the drugs are distributed). Pursuant to 21 U.S.C. § 356a, drug manufacturers could implement a change to the manufacturing process approved pursuant to an NDA or ANDA, and could distribute a drug made with the change, only if the manufacturer met certain requirements. These requirements included a supplemental application to the FDA or a report of the change to the FDA. 21 C.F.R. § 314.70 defined the requirements for reporting or submitting a

supplemental application to the FDA for a manufacturing change to an approved NDA. Pursuant to 21 C.F.R. § 314.97(a), these requirements also applied to manufacturing changes to an approved ANDA.[14]

Under 21 C.F.R. § 314.70(b)(1), a manufacturer was required to submit a Prior Approval Supplement for any major change. A major change was defined as a change that had a *substantial potential* to have an adverse effect on the identity, strength, quality, purity, or potency of a drug product as these factors may relate to the safety or effectiveness of the drug product—a standard clearly met here where the change resulted in an adverse effect documented by the FDA—the API was adulterated. Prior to distribution of the drug product made using the change, the manufacturer must obtain FDA approval of the supplement. A change to source of the manufacturing site of the API is such a change requiring FDA approval.

Moreover, the evidence will show that the defendants were aware of the requirement to file a supplement for the change in API manufacturer and simply chose to ignore it. *See Moyer*, 674 F.3d at 211 (holding that void-for-vagueness challenges are unavailable "in any specific case where reasonable persons would know their conduct puts [them] at risk of punishment under the statute"). The defendants knew that the API from the new manufacturer had a substantial potential to have an adverse effect on the drug product because the FDA found the API manufactured by the new manufacturer to be adulterated and issued a Warning Letter. ECF 4 at 9 (Overt Act Paragraph 7). It is noteworthy that the defendants did not express a lack of clarity on this issue to the FDA inspectors or the FDA Compliance Branch. Instead, they

[14] There is no dispute that for the purpose of these regulations, a drug substance includes API. 21 C.F.R. § 314.3(b).

blamed a former employee for failing to ensure that the required approvals were sought. The ANDA holders' obligations are so well-established on this issue that if KVK argued to the FDA that the requirements were too vague to understand, there is little doubt that the FDA would have had grave concerns about KVK's fundamental competence to manufacture prescription drugs.

KVK also argues that a Field Alert Report ("FAR") was not required; that the lack of an adulteration charge in the Superseding Indictment is an admission that the drugs were not adulterated; and that the government acknowledged that the DRL material was materially identical to UCB material when it accepted KVK's supplement in 2014, "confirming that the DRL and UCB products are interchangeable." ECF 96-1 at 23. All three arguments are without merit.

Under 21 C.F.R. § 314.98, ANDA holders must comply with the reporting requirements in 21 C.F.R. § 314.81, including the requirement in 21 C.F.R. § 314.81(b)(1) to submit FARs for, among other things, any significant change in a distributed drug product or the failure of one or more distributed batches to meet the specifications established in the application. The 62 batches of Hydroxyzine distributed by KVK containing HCL API from DRL in Mexico did not meet the specifications in the ANDA. KVK acknowledged its obligation to file a FAR when it filed one for Hydroxyzine after the FDA inspectors uncovered the violations impacting the drug.

Moreover, the lack of an adulteration charge in the indictment is by no means a concession that the drugs manufactured with DRL API were identical to the drugs manufactured with UCB API. It is black letter law that the government is not required to charge every applicable crime. Moreover, the fact that all Hydroxyzine tablets manufactured

with DRL API were recalled from the market underscores the absurdity of this argument.

The FDA's approval of DRL API in 2014 had no relation to the quality of the DRL API used by KVK in 2011 and 2012. By 2014, the FDA determined that DRL in Mexico had remediated the violations at its Morelos manufacturing facility and had implemented sufficient cGMP safeguards to ensure the quality and effectiveness of its drug substances. If KVK had obeyed the law and sought FDA approval to use DRL's API in 2011 and 2012, the request would have been denied due to the significant cGMP issues at the Morelos facility which were resolved by 2014 when KVK belatedly submitted its ANDA supplement for Hydroxyzine to include DRL in Mexico as an API source.

3. Hydroxyzine Made with DRL API Was an Unapproved Drug

Finally, KVK argues that a failure to obtain approval to use DRL API did not transform Hydroxyzine into an unapproved new drug. ECF 96-1 at 23. According to the defendants, KVK's ANDA remained in effect, the FDA never sought to withdraw it, and even if the FDA did want to withdraw the ANDA, KVK's failure to file a supplement is not grounds for withdrawal. ECF 96-1 at 23-27. This argument completely fails to understand the simple premise that KVK's Hydroxyzine containing HCL API made by DRL in Mexico was not mentioned in the ANDA and therefore not covered by the ANDA. The FDA approved KVK's ANDAs for Hydroxyzine manufactured with API made at either UCB's facility in Belgium or Cosma's facility in Italy. The drugs manufactured with API from DRL were different drugs and not subject to the approved ANDAs. Therefore, the Hydroxyzine containing API from DRL in Mexico was unapproved and did not have an approved ANDA to withdraw.

Under 21 C.F.R. § 314.50(d)(1)(i) (applicable to ANDAs under 21 C.F.R. § 314.94(a)(9)), an ANDA must include detailed information about the drug substance (API),

including "its physical and chemical characteristics and stability; the name and address of its manufacturer; the method of synthesis (or isolation) and purification of the drug substance; the process controls used during manufacture and packaging; and the specifications necessary to ensure the identity, strength, quality, and purity of the drug substance." Once the ANDA is approved, the approval applies only to drugs that meet the requirements set forth in that ANDA. *See, e.g.*, *United States v. Genendo Pharm., N.V.*, 485 F.3d 958 (7th Cir. 2007); *In re Canadian Import Antitrust Litigation*, 470 F.3d 785 (8th Cir. 2006). These cases discuss that the FDA drug review process encompasses safety and effectiveness, labeling, chemical composition, and manufacturing processes, among other things. To be considered "approved," a drug must be manufactured and labeled in accordance with the information provided in the NDA (or ANDA).

A similar theory is sometimes used in "off-label" promotion cases, where approved drugs are sold by the NDA holder for indications not included in the NDA. In such cases, the FDA does not move to withdraw the NDA, because the new indication takes the drug outside the scope of the NDA and causes it to be an unapproved new drug. The fact that there are no grounds for withdrawal of existing NDAs for failing to file a supplement supports the government's position that the drugs are unapproved new drugs. Otherwise, there would be no violation, and no remedy, for an applicant's failure to file a supplement for a major change to an approved drug.

KVK's Hydroxyzine contained an active ingredient outside of its approved ANDA. Thus, KVK distributed a drug without an approved ANDA making it an unapproved drug. This is not a novel theory.

Congress has carefully crafted a regulatory system in the FDCA to ensure that drugs marketed in the United States, prescribed by health care professionals and taken by patients, are

safe and effective for each of their intended uses. This regulatory system includes: (1) detailed requirements for a New Drug Application (NDA and ANDA), *see* 21 U.S.C. § 355, (2) regulatory oversight of the manufacturing and packaging processes and facilities, and any changes made to an approved drug, *see* 21 U.S.C. § 356a, (3) compliance with current good manufacturing practice requirements, *see* 21 U.S.C. § 351(a)(2)(B), and (4) restrictions on the importation of prescription drugs, *see* 21 U.S.C. § 381. Each part of this regulatory system plays an important role in ensuring the safety and efficacy of drugs distributed to American consumers.

A new drug may not lawfully be distributed in interstate commerce in the United States unless "an approval of an application filed pursuant to [21 U.S.C. § 355(b) or (j)] is effective with respect to such drug." 21 U.S.C. § 355(a). A New Drug Application filed under this section must include extensive clinical and other data to establish the drug's safety and efficacy. 21 U.S.C. § 355(b). These other data include: "a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug"; specifications related to, among other subjects, containers and closure systems, packaging materials and methods; and the specific product labeling. 21 U.S.C. § 355(b)(1); 21 C.F.R. § 314.50.

These statutory requirements reflect "a congressional view that the way in which drugs are mixed and packaged is no less important than the chemical makeup of the drugs." *United States v. Baxter Healthcare Corp.*, 901 F.2d 1401, 1411 (7th Cir. 1990). The FDA's approval of a New Drug Application—and thus, the FDA's decision concerning the safety and efficacy of the new drug—is based on the total of all information contained in the application. Once approved, a new drug must be manufactured, packaged, and labeled in conformance with each

element of the approved New Drug Application in order to be introduced into interstate commerce. 21 U.S.C. § 331(d).

Significantly, after the FDA approves a New Drug Application, any changes made in the production of the drug differing from the conditions in the application are subject to regulatory oversight. *See* 21 U.S.C. § 356a ("Manufacturing Changes"); 21 C.F.R. § 314.70 ("Supplements and other changes to an approved application"). If a company wants to distribute in the United States a drug with a component that was manufactured or packaged in a facility not identified in its approved New Drug Application, it must comply with applicable regulations governing such a change, must notify FDA of the change, and, in many cases, await FDA approval. *See, e.g.*, 21 C.F.R. § 314.70. The company would violate the law if it marketed the drug in the United States without notifying the FDA about the new manufacturing or packaging facility. Subsequently, the FDA may choose to inspect such a new facility to determine whether its operations are in compliance with the FDCA, agency regulations, and the drug's approved New Drug Application.

As the above make abundantly clear, the defendants' arguments attempt to parse the FDCA to an absurd result. The ANDA for Hydroxyzine allowed KVK to manufacture the drug using API manufactured by UCB at its facility in Belgium. Per KVK's application, the UCB site was ready for FDA inspection. It is clear that the approval was site-specific, which makes good sense: the FDA inspects the facilities to ensure compliance with cGMP which encompasses a comprehensive quality system involving facility cleanliness, materials labeling and storage, operator qualifications and training, proper documentation and record-keeping, manufacturing machinery maintenance, quality control sampling procedures, and drug formula consistency. A cGMP system provides assurance that drugs or, in the case of API, drug substances, are safe and

effective for use in drugs consumed by U.S. citizens. Thus, the defendants are correct that KVK did not lose its authorization to market Hydroxyzine pursuant to the existing ANDA, provided the drugs were made with API manufactured by the UCB facility in Belgium. But the existing ANDA did not constitute FDA approval for Hydroxyzine made with any other API, and therefore such drugs were unapproved.

B. KVK's Agents Are Properly Alleged to Have Conspired with One Another

Agents of a corporation can, of course, conspire with one another and/or other parties, and the corporation can be held vicariously liable for the conspiratorial actions of a culpable corporate agent or agents. *See, e.g.*, *United States v. Sain*, 141 F.3d 463, 475 (3d Cir. 1998) ("[A] corporation is a conspirator only pursuant to respondeat superior liability. If an agent of the corporation conspires with another individual, the corporation for which the individual is the agent may be criminally liable. However, there must be at least two natural individuals for a conspiracy involving a corporation to exist because two entities must have the required mental state to form a conspiracy."); *United States v. Basroon*, 38 Fed. App'x 772, 781 (3d Cir. 2002); *United States v. Hugh Chalmers Chevrolet-Toyota, Inc.*, 800 F.2d 737, 738 (8th Cir. 1986); *United States v. Consolidated Coal Co.*, 424 F. Supp. 577, 579-81 (S.D. Ohio 1976) (distinguishing *United States v. Carroll*, 144 F. Supp. 939 (S.D.N.Y. 1956)). This is exactly what is contemplated by Third Circuit Pattern Jury Instruction 7.06, Corporate Criminal Responsibility (Nov. 2018).

In an effort to undermine this theory of liability, KVK attempts to muddy the issue by citing cases applying the intra-corporate conspiracy doctrine and suggesting that this doctrine should control in this case. *See* ECF 96-1 at 28.[15] Multiple circuits, however, have declined to

[15] The cases that defendant KVK cites in support of its argument stand for the unremarkable proposition that a corporation cannot conspire with its agent, but none of these

extend this civil doctrine to criminal activity. *See, e.g.*, *United States v. St. John*, 625 Fed. App'x 661, 665 n.2 (5th Cir. 2015) ("it is well-accepted that the intracorporate conspiracy doctrine does not apply in the criminal context"); *United States v. Hughes Aircraft Co.*, 20 F.3d 974, 979 (9th Cir. 1994) ("[T]his doctrine has never been applied to criminal cases."); *United States v. Ames Sintering Co.*, 927 F.2d 232, 236-37 (6th Cir. 1990); *United States v. Stevens*, 909 F.2d 431, 432-33 (11th Cir. 1990); *Hugh Chalmers*, 800 F.2d at 738; *McAndrew v. Lockheed Martin Corp.*, 206 F.3d 1031, 1035-41 (11th Cir. 2000) (while discussing doctrine extensively, noting "the long-established conclusion that the intracorporate conspiracy doctrine does not apply to criminal conspiracies"). Moreover, the Third Circuit does not even recognize this doctrine in the civil context. *See Basroon*, 38 Fed. App'x at 781 (citing *Novotny v. Great Am. Fed. Sav. & Loan Ass'n*, 584 F.2d 1235, 1256-59 (3d Cir. 1978), *vacated on other grounds*, 442 U.S. 366 (1979)). And to be clear, the indictment does not allege that KVK conspired with its agents, but rather that the corporation is liable for the unlawful conduct of its agents under respondeat superior. Thus, defendant KVK's challenge must fail.

C. <u>The Mail Fraud Count Should Not Be Dismissed</u>

Count Two of the Superseding Indictment comports with the requirements of Rule 7 and is therefore sufficient. Fed. R. Crim. P. 7(c)(1). The defendants do not allege otherwise. Instead, they once again improperly seek to dismiss an indicted charge based on factual assertions not contained in the indictment.

The defendants seek dismissal of the mail fraud charge (Count Two) based upon the assertion that because KVK issued a public recall notice, Customer 1 was not defrauded as to KVK's use of unapproved API manufactured by DRL in Mexico. ECF 96-1 at 29. Specifically,

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decisions hold that a corporate cannot be held vicariously liable for the conspiratorial actions of its agents. *See* ECF 96-1 at 28.

the defendants contend that by the time that Customer 1 initiated the wire transfer in Count Two, the defendants had disclosed the relevant information to the customer through the recall notice issued on December 9, 2013. Whether Customer 1 was in fact defrauded, and the ultimate significance of the recall notice considered in the context of any other communications between KVK and Customer 1 (including KVK's misrepresentations) are factual questions to be determined only after the government has had a chance "to marshal and present its evidence at trial." *DeLaurentis*, 230 F.3d at 661. With this argument, the defendants again invite the Court to ignore the well-established principle that "a pretrial motion to dismiss an indictment is not a permissible vehicle for addressing the sufficiency of the government's evidence." *Id.* at 660. The Court should decline this invitation.[16]

Moreover, even if the Court were to accept the defendants' invitation to go beyond the "narrow, limited analysis" of the facial sufficiency of the indictment, the defendants' motion would still fail. *Vitillo*, 490 F.3d at 321. The defendants succinctly offer their argument as: "Because the public record conclusively shows that [Customer 1] was not defrauded, the mail fraud count must be dismissed." ECF 96-1 at 30. Even if their assertion were true (that Customer 1 was not ultimately defrauded), it would not provide a basis for dismissing the mail fraud charge because "[n]either the ultimate success of the fraud nor the actual defrauding of a victim is crucial to a successful prosecution." *United States v. Keane*, 522 F.2d 534, 545 (7th

[16] Although not at issue on this motion to dismiss, the defendants' factual argument is also entirely without merit. It ignores the crucial fact that the defendants distributed unapproved Hydroxyzine that they passed off as an FDA-approved drug. In fact, the defendants had sold unapproved Hydroxyzine to its customers, including Customer 1, for more than two years before the FDA discovered the violation and the recall. At no time did the defendants inform KVK's customers that they had been sold an unapproved drug that could not be legally distributed. Instead, the recall notice, when it finally was issued, only referred to a vague "regulatory filing requirement for the API."

Cir. 1975); *see United States v. Copple*, 24 F.3d 535, 544 (3d Cir. 1994) ("Proof of actual loss by the intended victim is not necessary."); *United States v. Warshak*, 631 F.3d 266, 310 (6th Cir. 2010) ("Notably, the mail . . . fraud statute[] do[es] not require proof that the intended victim was actually defrauded; the actual success of a scheme to defraud is not an element of . . . § 1341 . . . ."") (internal quotation omitted); *United States v. Dunning*, 929 F.2d 579, 581 (10th Cir. 1991) ("[T]he gist of [mail fraud] is devising a scheme to defraud with a purpose of executing the scheme; the ultimate success or failure of the scheme is immaterial."); *United States v. Forzese*, 756 F.2d 217, 221 (1st Cir. 1985) ("success or failure of the scheme is irrelevant to criminal liability under the statute"); *United States v. Pollack*, 534 F.2d 964, 971 (D.C. Cir. 1976) ("Since success of the scheme and loss by a defrauded person are not essential elements of the crime under 18 U.S.C. §§ 1341, 1343, allegations of such consequences are unnecessary to a proper indictment."). The indictment here alleges that KVK devised a scheme to defraud and that to carry out that scheme, KVK used the mail. Nothing more is required. *See, e.g.*, *United States v. Yusuf*, 536 F.3d 178, 187 (3d Cir. 2008) ("Stated plainly, the elements necessary to establish the offense of mail fraud are (1) a scheme or artifice to defraud for the purpose of obtaining money or property and (2) use of the mails in furtherance of the scheme. Therefore, once these two requirements are met, mail fraud has been committed.").

The defendants' arguments regarding materiality are likewise irrelevant to this inquiry. Materiality is an evidentiary issue for the fact finder. *See United States v. Gaudin*, 515 U.S. 506 (1995) (materiality is an issue to be determined by the jury); *United States v. White*, No. 04-CR-00370, 2004 WL 2612017, at 12 (E.D. Pa. Oct. 29, 2004) (citing *United States v. Neder*, 527

U.S. 1 (1999), for proposition that materiality in fraud charge must be determined by the jury).[17] Although the defendants speculate that Customer 1 determined that FDA approval of Hydroxyzine was immaterial to their purchasing decision, ECF 96-1 at 31, evidence at trial, which has been disclosed to the defendants, will show otherwise. Such evidence to be adduced at trial includes, for example, Customer 1's purchasing agreement with KVK, in which KVK falsely represented that any drug purchased by Customer 1 would comply with all FDA regulations. While KVK may disagree with what the evidence shows, the defendants will have the opportunity to make their case to the jury at trial—but not at this stage of the proceedings.

For the reasons above, mail fraud is properly charged in the indictment and not subject to dismissal.[18]

II. DEFENDANTS' MOTIONS TO DISMISS COUNT ONE AS TIME-BARRED SHOULD BE DENIED

The efforts of defendants Vepuri and Panchal to seek dismissal of the conspiracy count on statute of limitations grounds should be rejected. First, they erroneously attempt to recast the

[17] In support of their argument, the defendants rely on two civil actions discussing materiality as applied under the False Claims Act. ECF 96-1 at 30-31. These cases were brought under a completely different statute, determined under an entirely different standard (including summary judgment), and presented completely different facts than the motion to dismiss the criminal indictment in this case. They should be disregarded.

[18] The defendants again mischaracterize the FDA's position claiming that it acknowledged when it approved KVK's supplement for the DRL material in 2014 that the API was identical to UCB in all material respects. ECF 96-1 at 31. That is not the case. Comparing the 2014 material to the 2011 material is apples to oranges. The materials are not the same, and FDA never concluded that they were. For the reasons already explained, these materials were not equivalent.

central objectives of the conspiracy far more narrowly than is actually alleged. Second, defendant Panchal prematurely asks the Court to make evidentiary findings.[19]

A. The Applicable Limitations Periods

As this Court is well aware, the applicable statute of limitations for a conspiracy charge under 18 U.S.C. § 371 is five years. 18 U.S.C. §3282(a). Conspiracy is a continuing offense, and the limitation period does not begin to run until the completion of the last overt act that is part of the offense. *See United States v. Amirnazmi*, 645 F.3d 564, 592 (3d Cir. 2011) (quoting *United States v. Jake*, 281 F.3d 123, 129 n.6 (3d Cir. 2002)); *United States v. Fattah*, 223 F. Supp. 3d 336, 353 (E.D. Pa. 2016) (Bartle, J.).

Here, the Superseding Indictment was filed on June 10, 2021. Normally, this would mean that an overt act must have occurred on or after June 10, 2016. Because, however, the Honorable Cynthia M. Rufe issued a tolling order under 18 U.S.C. § 3292(a), this limitations period was tolled for six months. ECF 94 at 10; ECF 102 at 26-27. Furthermore, each defendant executed agreements with the government tolling the statutes of limitations for a period of time, also changing the analysis.

For instance, KVK entered five separate statute of limitations waivers, starting on May 28, 2019, and lasting through June 14, 2021. Accordingly, this time was tolled under the applicable statutes of limitations. As a result, for the conspiracy charge against KVK to be timely the last overt act must have occurred on or after November 19, 2013.[20] None of the defendants, however, have argued that the overt acts set forth in paragraphs 14 and 15 of Count

[19] Defendant KVK has moved to join these motions, but for the reason explained below, the arguments do not apply to KVK.

[20] Defendant KVK has not challenged the timeliness of Count Two (wire fraud).

One, alleged to have occurred in December 2013, were untimely. Thus, because these acts occurred within the limitations period applicable to KVK, its joined dismissal argument regarding timeliness should be summarily dismissed.

Defendant Vepuri also entered five statute of limitations waivers with the government. The first of these waivers started on September 9, 2019, and these waivers extended the statute of limitations until at least May 17, 2021.[21] As a result, there is no dispute that the conspiracy charge against Vepuri is timely if the last overt act occurred on or after April 2, 2014. ECF 94 at 11. As explained below, the overt acts alleged in Overt Act Paragraphs 16 through 19 fall within this period.

Finally, defendant Panchal entered four statute of limitations waivers with the government. These waivers tolled the limitations period from June 8, 2020 through June 14, 2021. Accordingly, for the conspiracy charge against Panchal to be timely, the last overt act must have occurred on or after December 8, 2014. Two overt acts alleged in the superseding indictment fall within this period: the overt acts alleged in Overt Act Paragraphs 18 and 19.

B. Vepuri and Panchal Misconstrue the Conspiracy Charge When Arguing that Its Objective Was Achieved in December 2013

Confronted with these facts, defendants Vepuri and Panchal misconstrue the Superseding Indictment to argue that the overt acts set forth in Overt Act Paragraphs 16 through 19 were merely acts of concealment and not acts in furtherance of the central objectives of the conspiracy

[21] The government believes that these waivers tolled the statute of limitations until June 14, 2021, which was clearly the intent of the parties, while KVK has apparently taken the position that the fifth waiver was ineffective for some reason. The Court, however, need not resolve this disagreement because the difference should not affect the Court's statute of limitations analysis.

and, thus, did not extend the statute of limitations. As explained below, this gambit should be rejected.

In service of their argument, defendants Vepuri and Panchal recount the Supreme Court's well-established holding from *Grunewald v. United States* that "the crucial question in determining whether the statute of limitations had run is the scope of the conspiratorial agreement." 353 U.S. 391, 397 (1957). They effectively ignore, however, another central lesson from *Grunewald*, which is dispositive here: "a vital distinction must be made between acts of concealment done in furtherance of the main criminal objectives of conspiracy, and acts of concealment done after these central objectives have been attained, for the purpose only of covering up after the crime." *Id.* at 406. The Supreme Court explained that acts of concealment done in furtherance of the main objectives of the conspiracy will extend the period of the conspiracy, but acts of concealment committed after the central objective have been attained will not. *Id.* at 406-09; *see United States v. Fattah*, 223 F. Supp. 3d 335, 353 (E.D. Pa. 2016) (Bartle, J.).

In ignoring this principle, defendants Vepuri and Panchal make exactly the mistake that *Grunewald* warns against. They construe the conspiracy set forth in Count One far more narrowly than it is alleged in the Superseding Indictment and then argue that the relevant overt acts (in Overt Act Paragraphs 16 through 19) did not further this improperly narrowed conspiracy. For example, instead of addressing the charging language in Paragraph 16 of Count One setting forth the objectives of the conspiracy or addressing the Manner and Means alleged in Paragraphs 17 and 18, ECF 4 at 6-7, defendant Vepuri focuses exclusively on a single sentence in one overt act paragraph to argue that the central objective of the conspiracy was narrower than

that alleged, ECF 94 at 8 (quoting Overt Act Paragraph 9 of Count One). Defendant Panchal makes the same mistake. ECF 102 at 19 (same).

A plain reading of the Superseding Indictment demonstrates the error. Count One does not merely allege a conspiracy to distribute unapproved product ending in December 2013, as the defendants suggest. Instead, it alleges a much broader conspiracy to defraud the United States and its agencies by impeding, impairing, and defeating the lawful functions of the FDA to protect the health and safety of the public by ensuring that drugs marketed and distributed in the United States were safe and effective for their intended uses. ECF 4 at 5. It also alleges two additional objectives, only one of which is the central objective that the defendants identify: (1) with the intent to defraud and mislead, introducing or delivering for introduction, and causing the introduction or delivery for introduction, into interstate commerce of unapproved new drugs in violation of 21 U.S.C. §§ 331(d), 355(a); and (2) knowingly and willfully making materially false, fictitious, and fraudulent statements and representations, and falsifying and concealing material facts in a matter within the jurisdiction of the FDA, an agency of the executive branch of the United States, in violation of 18 U.S.C. § 1001. *Id.* Moreover, these allegations span longer than the period suggested by the defendants, starting in October 2010 and lasting until at least March 2015. *Id.*

In addition, the Manner and Means section of Count One demonstrates that the alleged conspiracy was broader than simply the single sentence of one overt act that the defendants assert. For instance, Paragraph 17 of the Manner and Means section alleges that (i) defendant Vepuri represented that he was an advisor and a part-time consultant to KVK when, in fact, he exercised unchecked authority over the company, (ii) Vepuri acted through Panchal and others on matters related to drug manufacturing and regulatory requirements, and (iii) Panchal carried

out orders at Vepuri's direction. *Id.* at 7. Notably, this is exactly the deception that is alleged in Overt Act Paragraph 17. *Id.* at 13 (alleging on or about June 27, 2014, Vepuri misled the FDA regarding his role at KVK).

Paragraph 18 of the Manner and Means section of the conspiracy count contains similarly broad allegations. *Id.* at 7. It alleges that KVK ignored FDA regulatory requirements that had the potential to slow or interfere with the manufacture and distribution of its drug Hydroxyzine and, through Vepuri and Panchal, provided false information to excuse those violations. *Id.* Specifically, Paragraph 18 alleges that through Vepuri and Panchal, KVK "provided false explanations to the FDA when inspectors identified violations," "falsely attributed intentional regulatory failures to a mistake or misunderstanding," and "falsely assure[d] the FDA that violations had been addressed and correction actions was being taken when, in fact, and as they well knew, no corrective and preventative actions were taken." *Id.*

Again, this is exactly what is alleged in the overt acts challenged by defendants Vepuri and Panchal. For instance, Overt Act Paragraph 16 directly addresses this objective, alleging that during a June 27, 2014 meeting, Vepuri and Panchal intentionally misled the FDA regarding KVK's use of the unapproved API and continued to attribute the regulatory failure to "a mistake by a former employee." *Id.* at 13. Likewise, Overt Act Paragraph 18 alleges that on or about December 11, 2014, Panchal provided a false and misleading report regarding the causes of the regulatory failures. *Id.* at 13-14. And finally, Overt Act Paragraph 19 alleges that the defendants failed to notify the FDA of the falsehoods that they had caused to be included in an FDA report through their deception. *Id.* at 14.

Thus, an analysis of the Superseding Indictment reveals that the central objectives of the alleged conspiracy were far broader than the defendants suggest. It was not merely a conspiracy

to distribute unapproved drugs, as the defendants contend. Rather, the conspiracy's central objectives included defrauding the FDA by concealing KVK's illegal use of the unapproved API from FDA and making false statements to the FDA. The defendants' acts in furtherance of these objectives started before the API was purchased, persisted while it was being used to manufacture and distribute the drug, and continued after the distribution was finished. They included the defendants' efforts to conceal from the FDA critical facts about Vepuri's role at KVK and the company's use of the unapproved API. Overt Act Paragraphs 16 through 19 allege just such conduct by the defendants.

For this reason, defendant Vepuri's attempt to analogize this case to *United States v. Roshko*, 969 F.2d 1 (2d Cir. 1992), fails. ECF 94 at 15. There, the Second Circuit understandably concluded that where the defendant was charged with conspiring to adjust his immigration status by entering into a sham marriage, overt acts relating to his subsequent divorce and remarriage did not extend the conspiracy because they were not related to the object of the conspiracy: obtaining a green card through a sham marriage. *Roshko*, 969 F.2d at 8. In contrast, here the conspiracy alleged was far broader. The Superseding Indictment charges a conspiracy to defraud the FDA and to make various false and misleading representations to the agency to conceal Vepuri's role and KVK's use of an unapproved API. As a result, the overt acts in furtherance of these broad objectives extend the statute of limitations and make the conspiracy charge in Count One timely.

Indeed, this case is far more similar to one of the other cases cited by defendants Vepuri and Panchal, one of this Court's decisions in *United States v. Fattah*, 223 F. Supp. 3d 335 (E.D. Pa. 2016). In that decision, the Court found that certain campaign filings concealing the fraudulent nature of an invoice "were clearly a central aim of th[e] conspiracy" to maintain the

defendant as a viable political figure. 223 F. Supp. 3d at 354. Similarly, the defendants' efforts in 2014 and 2015 to mislead the FDA regarding KVK's use of unapproved API and Vepuri's role at KVK certainly furthered the central aims of the conspiracy to impede and provide false information to the FDA, and thereby enable KVK to maintain viability in the drug business. *Compare* ECF 4 at 6-7 to *id.* at 13-14.

Even more relevant is the Third Circuit's decision in *United States v. Moses*, 148 F.3d 277 (3d Cir. 1988), also involving a conspiracy to defraud the United States. The *Moses* court found *Grunewald* "wholly distinguishable" because although the main objective of *Grunewald* was narrow and the government sought "to imply" a later subsidiary conspiracy to conceal, the indictment in *Moses* charged a conspiracy to defraud and it alleged overt acts in furtherance of the conspiracy to defraud within the limitations period. *Id.* at 282 (explaining that conspiracy continued until fraud upon the government was "permanently effected"). The situation is no different here.

Thus, Count One is not barred by the statute of limitations because these overt acts, alleged in Overt Act Paragraphs 16 through 19, occurred as part of the plan of the conspiracy.[22]

C. The Superseding Indictment Adequately Alleges Overt Acts Occurring on or about December 11, 2014

Defendant Panchal's contention that the overt acts alleged in Overt Act Paragraphs 17 and 18 are insufficient must be rejected. *See* ECF 102 at 25-26. The standard to be applied is

[22] Other cases that defendant Vepuri cites also support the timeliness of the alleged overt acts. For instance, although the Fifth Circuit's decision in *United States v. Davis* concluded that the conspiracy charge was time barred, it did so because "[t]he sole object of the conspiracy as charged was to make false statements and representations" to a government agency and was not a conspiracy to defraud the United Sates. 533 F.2d 921, 928 (5th Cir. 1976). Of course, here just the opposite is true: one of the objectives of Count One is to defraud the United States. Similarly, in *United States v. Borman*, the Third Circuit noted that had indictment been drafted

clear. Under Federal Rule of Criminal Procedure 12(b)(1), "[a] party may raise by pretrial motion any defense, objection, or request that the court can determine without a trial on the merits." Thus, "[w]here a defendant brings a pre-trial motion to dismiss on statute of limitations grounds, 'a district court must accept as true the factual allegations set forth in the indictment' to determine whether a jury could find that the defendant committed the offense for which he was charged within the limitations period." *United States v. Weigand*, No. 5:17-CR-00556, 2021 WL 1424728, at *3 (E.D. Pa. Apr. 15, 2021) (citing *United States v. Smukler*, 330 F. Supp. 3d 1050, 1054 (E.D. Pa. 2018) (quoting *United States v. Huet*, 665 F.3d 588, 595-96 (3d Cir. 2012))); *see United States v. Kogan*, 283 F. Supp. 3d 127, 134–35 (S.D.N.Y. 2017) ("In the specific context of a motion based on statute of limitations grounds, a pre-trial motion to dismiss is premature if the indictment is facially sufficient and the defendant's argument in favor of dismissal requires a determination of factual issues."); *United States v. Hoskins*, 73 F. Supp. 3d 154, 159, 160 (D. Conn. 2014) (same); *United States v. FNU LNU*, No. 06-CR.-846, 2007 WL1149261, at *2 (S.D.N.Y. Apr. 12, 2007) (same).

Despite this clear law, defendant Panchal now asks the Court to ignore this well-established principle and undertake a factual analysis of the overt acts alleged in Overt Act Paragraphs 17 and 18. There is no reason to do so. These paragraphs clearly allege conduct occurring on or about December 11, 2014. If this conduct is proven at trial, the conspiracy charge against defendant Panchal will be timely.

No doubt recognizing this controlling principle, Panchal cites a Tenth Circuit case to argue that the Court can consider evidence on a motion to dismiss. ECF 102 at 25 n.6 (citing

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more broadly (as the Superseding Indictment was here), its decision would have different. 559 F.3d 150, 153-54 (3d Cir. 2009).

United States v. Todd, 446 F.3d 1062, 1068 (10th Cir. 2006)). This case, however, does not stand for this broad proposition. Rather, it states:

> In "limited circumstances," the Tenth Circuit has held that a district court may "dismiss charges at the pretrial stage . . . where the operative facts are undisputed and the government fails to object to the district court's consideration of those undisputed facts in making the determination regarding a submissible case."

446 F.3d at 1068. *Todd* proceeds to explain that "[d]ismissal in this manner is the 'rare exception,' not the rule." *Id.* The Tenth Circuit then adds: "Dismissals under this exception are not made on account of a lack of evidence to support the government's case, but because undisputed evidence shows that, as a matter of law, the Defendant could not have committed the offense for which he was indicted." *Id.*

None of these "limited" circumstances are applicable here. The operative facts are disputed by the government. And the government does hereby object to the consideration of the facts alleged by defendant Panchal, facts which are disputed. Accordingly, the Court must find, as a matter law, that Count One is not time barred because of the alleged factual dispute regarding Overt Act Paragraphs 17 and 18.[23]

D. Defendants' Conduct in March 2015 Was an Actionable Overt Act

As the defendants recognize, a failure to act or an omission can be an overt act, where the co-conspirator who failed to act had a legal duty to perform the act and he or she omitted

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[23] Although now is not the time for the Court to resolve this factual dispute, it should be noted that defendant Panchal's argument is based upon a faulty premise. Panchal references notes taken during an inspection of KVK that occurred from November 17, 2014 through December 11, 2014 and points to a notation apparently taken on November 20, 2014, indicating that the report discussed in Overt Act Paragraph 18 was requested on this date. ECF 102 at 25; *id.* ex. A at 6. This notation is a circle with the number of the report next to it. *Id.* ex. A at 6. The circle has a diagonal line through it, which Panchal assumes means that the report was received on the date that it was requested. *See* ECF 102 at 25. Nothing about this note shows that KVK provided the false and misleading report on the date that it was requested.

performance in order to further the achievement of the objectives of the conspiracy. *See* Third Circuit Pattern Criminal Jury Instruction 6.18.371F, comment (citing *United States v. Curran*, 20 F.3d 560 (3d Cir. 1994)).[24] Here, the Superseding Indictment alleges just such a failure in Overt Act Paragraph 19. ECF 4 at 14 (alleging: "After the FDA released a final Establishment Inspection Report ("EIR") for the second inspection on or about March 2, 2015, defendants KVK-TECH, MURTY VEPURI and ASHVIN PANCHAL, knowing the EIR was substantially false based on information they had provided, failed to notify the FDA of the falsehoods to avoid enforcement action or being required to perform needed corrective actions.").

Vepuri's and Panchal's duty to disclose in Overt Act Paragraph 19 arose from two separate bases. First is the duty to disclose information to the FDA, specifically, truthful information required to be disclosed by the FDCA and FDA regulations. *See, e.g.*, *McLaughlin v. Bayer Corporation*, 172 F. Supp. 3d 804, 825-26 (E.D. Pa. 2016) (finding in plaintiff's fraudulent concealment claim that the duty to disclose "is a federal duty to disclose information to the FDA," and that the claim was therefore federally preempted); *see also Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 348-53 (2001) (discussing the FDA's broad authority to require information disclosures and finding federal preemption applies because "fraud-on-the-FDA" claims exist "by virtue of the FDCA disclosure requirements").

Second, Vepuri and Panchal's duty in this case also arose from their positions at KVK. As responsible officials in positions of authority in a regulated company, they have a legal duty to implement whatever measures are necessary to ensure that their products, practices, processes, or other activities comply with the law. The Responsible Corporate Officer ("RCO") doctrine—

[24] Despite acknowledging this legal principle, defendants Vepuri and Panchal both cite several inapplicable civil conspiracy cases for the proposition that failure to act and omissions cannot be overt acts. ECF 94 at 15; ECF 102 at 24. These decisions have no bearing here.

also known as the "Park Doctrine"—imposes strict liability upon individual corporate officers for violations of the FDCA. In *United States v. Park*, the Supreme Court affirmed Park's conviction, reaffirming its prior decision—in *Dotterweich*—that an individual can be held criminally liable for an FDCA violation "without consciousness of some wrongdoing" if he bears a "responsible relationship to, or [has] a responsible share in, violations." *United States v. Park*, 421 U.S. 658 (1975); *see United States v. Dotterweich*, 320 U.S. 277 (1943). The Court further interpreted the FDCA as imposing upon corporate officers not only the duty to seek out and remedy known violations but also to implement measures to prevent violations. *Park*, 421 U.S. at 672. This created an affirmative duty with respect to the FDCA.

The Court held that a corporate officer is criminally liable under the FDCA when he has "responsibility and authority either to prevent in the first instance, or promptly to correct, the violation complained of" and fails to do so. *Id.* at 673-74. The FDCA imposes on a person exercising authority and supervisory responsibility reposed in them by a business organization not only a positive duty to seek out and remedy violations, but also, and primarily, a duty to implement measures that will ensure that violations will not occur, *id.* at 672, in order to make distributors of FDA-regulated products "the strictest censors of their merchandise," *Smith v. California,* 361 U.S. 147, 152 (1959), and the FDCA punishes "neglect where the law requires care, or inaction where it imposes a duty," *Morissette v. United States*, 342 U.S. 246, 255 (1952).[25]

[25] Similarly, other courts have found that the RCO doctrine imposes an affirmative duty to act for individuals in a position of corporate responsibility. *See, e.g.*, *United States v. Iverson*, 162 F.3d 1015, 1022-25 (9th Cir. 1998) (applying *Park* and *Dotterweich* in upholding jury instructions that a responsible corporate officer with knowledge, authority, and capacity to prevent a violation is liable under the Clean Water Act for failing to act affirmatively to prevent the violation); *United States v. Johnson & Towers*, 741 F.2d 662, 670 (3d Cir. 1984) (applying *Park* and *Dotterweich* in holding that knowledge of a person with a responsible position with the

Panchal, in his capacity as the head of Quality Assurance, operated as a RCO for KVK. As such he had a duty to identify, correct, and prevent violations of the Act. The FDA included Panchal's investigation report into the Hydroxyzine violations in the Establishment Inspection Report of KVK to demonstrate that the violations leading to the distribution of an unapproved drug had been corrected. Panchal concealed from the FDA that the report he provided was substantially false, thereby allowing the violations to continue. Panchal had a duty to prevent such violations from occurring but failed to act, thus committing the overt act alleged in Overt Act Paragraph 19. The charges against Panchal are thus clearly within the statute of limitations as established by both overt acts alleged in Over Act Paragraphs 18 and 19. *See* Section II.A-C*, supra*.[26]

III. DEFENDANTS' MOTIONS TO STRIKE SHOULD BE DENIED BECAUSE ALL OF THE CHALLENGED ALLEGATIONS ARE RELEVANT TO THE SUPERSEDING INDICTMENT

Pursuant to Federal Rule of Criminal Procedure 7(d), a court may strike surplusage from the indictment on the motion of the government or a defendant. The scope of the district court's discretion to strike material from an indictment under this rule is narrow. *United States v. Pharis*, 298 F.3d 228, 248 (3d Cir. 2002) (dissenting opinion) (citing *United States v. Oakar*, 111 F.3d 146, 157 (D.C. Cir. 1997)). Motions to strike surplusage are rarely granted. *United States v. Hedgepath*, 434 F.3d 609, 611 (3d Cir. 2006). Such motions may only be granted if it is clear that the allegations in the indictment are *both* irrelevant to the charge and prejudicial. *Id.* at 612;

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corporate defendant can be inferred in prosecution under the Resource Conservation and Recovery Act).

[26] Moreover, the government intends to charge Panchal in a second superseding indictment with Overt Acts in furtherance of an ongoing conspiracy to defraud the FDA that occurred after March 2015.

see also United States v. Rezaq, 134 F.3d 1121, 1134 (D.C. Cir. 1998); *United States v. Schweitzer*, No. CRIM.A.03-CR-00451-1, 2004 WL 1535793, at *3 (E.D. Pa. Feb. 26, 2004). This is an exacting standard, met only rarely. *Schweitzer*, 2004 WL 1535793, at *3; *United States v. Jordan*, 626 F.2d 928, 930 n.1 (D.C. Cir. 1980); *United States v. Eisenberg*, 773 F. Supp. 662, 700 (D.N.J. 1991).

Defendants Vepuri and Panchal moved this Court respectively to strike as surplusage Paragraph 4 and certain information in Paragraph 5 of the superseding indictment. ECF 93, 103. Since the defendants have not, and cannot, meet the legal standard for relief, their motions should be denied.

1. Vepuri's Allegation

According to Vepuri, Paragraph 4 of the Superseding Indictment is irrelevant, as the statements contained therein are not essential to proving the charged conspiracy, ECF 93 at 8, and because, although true, the statements would tarnish him and allow "jurors mistakenly to conclude that the uncharged conduct alleged in that paragraph helps to establish his guilt." ECF 93 at 9. A fair reading of Paragraph 4 shows otherwise. Specifically, Paragraph 4 states:

> Prior to the formation of defendant KVK-TECH, defendant MURTY VEPURI owned a generic drug manufacturer located in New Jersey, and an API manufacturer and supplier located in Newtown, PA. The New Jersey company was subject to an FDA restraining order because of regulatory violations. Accordingly, defendant VEPURI was knowledgeable about regulatory requirements placed on drug manufacturers, including that drug manufacturers shall identify, prevent, and correct deficiencies that can impact drug safety and efficacy.

The information above is completely relevant to the charged conduct as it not only demonstrates Vepuri's experience with, and knowledge and understanding of, the FDA's regulations for generic drug manufacturing, but more importantly explains why Vepuri continuously lied to the

FDA falsely representing that he was only a mere consultant for KVK when, in reality, he controlled the company and was its *de facto* owner.

KVK's motion to dismiss, ECF 96, which Vepuri joined, argues that FDA regulations regarding changes in API are unclear and confusing. KVK asserts that "the byzantine regulatory scheme undergirding the government's charges is simply too vague and unclear to serve as a basis for criminal liability" and that the "backdrop of confusion," "lack of clarity," and differing understandings of what constitutes established conditions cannot support criminal charges predicated on the idea that KVK's supplier's decision to subcontract production of material for API changed a "condition established" in KVK's ANDAs. ECF 96-1 at 20-22. Having signaled that a core tenet of his defense will be that he did not understand the FDA regulations, Vepuri cannot now legitimately claim that his prior experience as the owner and operator of a generic drug manufacturer, which was subject to FDA regulations, is irrelevant to the charges in this case. The depth and breadth of Vepuri's experience with FDA regulations is critical to demonstrating that his actions were knowing and intentional and would rebut any suggestion that his conduct was attributable to misunderstanding. Vepuri's decision to join KVK's vagueness arguments belies his assurances that his "general awareness of general regulatory requirements is not at issue, and will not be contested at trial." ECF 93 at 8.

While Vepuri claims that "the government can prove Mr. Vepuri's knowledge of FDA regulations through other, less prejudicial, and relevant evidence," ECF 93 at 8, this is not his decision to make. It also fails to acknowledge the larger point, which is that Paragraph 4 demonstrates Vepuri's motive to conceal his true involvement in KVK's operations. Vepuri disguised himself as a "consultant" to attempt to avoid personal responsibility for violations under the FDCA which he had experienced at Able Labs. By operating covertly, Vepuri could,

and did, routinely circumvent defendant KVK's established operating procedures without detection. Vepuri's prior experience with the FDA also taught him what to conceal from the agency to prevent regulatory actions and how to conceal it. There is no doubt that Vepuri's prior experience with the FDA as a generic drug manufacturer is directly relevant to charges in this case.

The determinative question underlying any motion to strike surplusage is not the potential prejudice, but the *relevance* of the allegation to the crime charged in the indictment. *See United States v. Jimenez*, 824 F. Supp. 351, 370 (S.D.N.Y. 1993) (emphasis added). If the evidence of the allegation is admissible and relevant to the charge, then despite prejudice, the language will not be surplusage. The concept of relevancy within an indictment is broad; the indictment need not comprise essential elements of the crime nor be essential to the charges, so long as it is generally relevant to the overall scheme charged in the indictment. *See United States v. Giampa*, 904 F. Supp. 235, 271–72 (D.N.J. 1995). Further, the inclusion of a "background" or "general allegations" section is a permissible method of providing the relevant context and circumstances surrounding fraud charges in order for the charges to be understood. *See Jimenez*, 824 F. Supp. At 370.

In his motion, Vepuri relies heavily on a decision in *United States v. Cooper* from the Western District of Virginia. 384 F. Supp. 2d 958 (W.D. Va. 2005). In *Cooper*, the district court granted the defendant's motion to strike, finding the defendant's history with environmental agencies was unnecessary to the charges in the indictment because it was not essential to making out a *prima facie* pleading of a violation and was unduly prejudicial. *Cooper*, however, is distinguishable. The indictment at issue in *Cooper* contained *twenty* separate paragraphs, which the court referred to as a "preamble," that the court ordered stricken as surplusage. *See* ex. 1

(*Cooper* indictment).[27] This is hardly comparable to the government's factual characterization of Vepuri's prior involvement with the FDA in Paragraph 4:

> Prior to the formation of defendant KVK-TECH, defendant MURTY VEPURI owned a generic drug manufacturer located in New Jersey, and an API manufacturer and supplier located in Newtown, Pennsylvania. The New Jersey company was subject to an FDA restraining order because of regulatory violations.

ECF 4 at 2. While this may be an inconvenient truth for Vepuri, it is highly relevant to his knowledge of the FDA regulations and his reasons for lying to the FDA about his role in KVK.

In this analysis, the Third Circuit has emphasized that "information that is prejudicial, yet relevant to the indictment, must be included for any future conviction to stand and information that is irrelevant need not be struck if there is no evidence that the defendant was prejudiced by its inclusion." *Hedgepeth*, 434 F.3d at 612. Thus, for a district court to properly strike material from an indictment, it must be "both irrelevant (or immaterial) and prejudicial." *Id*. Here, because the material is relevant, it cannot be stricken, even if it might put Vepuri in a negative light. But, in any case, any potential prejudice is minimized by the way the information is presented in the indictment. The potentially prejudicial statement is short, limited to a single

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[27] In *Cooper*, the court struck paragraphs 5, 6, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 24, 25, 26, 27, and 28. Moreover, *Cooper* employed a narrow standard of relevance which generally held as irrelevant statements in an indictment that were not elements of the offense charged. This narrow standard was specifically rejected by the district court in *United States v. Pacific Gas and Electric Co.*, Case No. 14-cr-00175, 2014 WL 4954040 (N.D. Cal. Sept. 29, 2014) (non-published) (declining to follow *Cooper*'s narrow standard of relevance for surplusage purposes because the approach in the Ninth Circuit has been to use a broader standard than the one articulated by the out-of-circuit court in *Cooper*).

The Eastern District of Pennsylvania also employs the broader interpretation of relevance. *See United States v. Goldner*, Crim. No. Action 21-229, 2021 WL 4776340 (E.D. Pa. 2021) (citing *United States v. Caruso*, 948 F. Supp. 382, 392 (D.N.J. 1996)) (where language in an indictment is not essential to the charges contained therein, the language will not be stricken as surplusage in cases where the language is relevant in a general sense to the overall scheme alleged in the indictment).

sentence: "The New Jersey company was subject to an FDA restraining order because of regulatory violations." The single statement is made in a simple and objective manner, with no elaboration or detail, much less any inflammatory matter. Defendant Vepuri cannot meet his burden, and his motion to strike must fail.

2. Panchal's Allegation

Panchal likewise argues that statements in Paragraph 5 of the Superseding Indictment should be stricken. ECF 103 at 3-4. Specifically, he complains that the following, although true, is irrelevant and prejudicial:

> At the time he was recruited by defendant VEPURI, defendant PANCHAL was a citizen of India. In or about January 2005, defendant KVK-TECH sponsored defendant PANCHAL for a H-1B Visa, which allowed nonimmigrant aliens to enter or remain in the United States for temporary work in a specialty occupation.

ECF 4 at 2. According to Panchal, it is not relevant if he was beholden to Vepuri for securing him a work visa. ECF 103 at 4. Panchal argues that whether he "was recruited by Mr. Vepuri in exchange for a work visa has no tendency to make the charges any more or less true." *Id.* In fact, the opposite is true. Panchal's immigration status in this country depended on his continued employment, and Vepuri's hold over Panchal as his employer and Visa sponsor is exactly the point. It shows why Panchal would conspire with Vepuri to violate FDA regulations and then conceal those violations, for which Panchal was in part responsible, from the FDA inspectors. At trial, the government plans to introduce evidence showing that KVK had a culture of ignoring regulatory requirements, which was created, in part, by Vepuri's employment of a significant number of employees from India whom KVK sponsored on H-1B visas. Vepuri was able to exercise greater control over KVK's workforce and to prevent whistleblowers from reporting violations to the FDA by employing vulnerable non-citizens.

Panchal attempts to meet the prejudice prong to strike for surplusage by generally alleging that these statements would "tarnish Mr. Panchal in the eyes of a jury." There is nothing inherently prejudicial or inflammatory about being born in India and/or working in the United States by virtue of an H-1B visa. *United States v. Ali*, No. Crim. 04-CR-661-2, 2005 WL 1993519, at *1 (E.D. Pa. Aug. 16, 2005) (motion to strike surplusage should only be granted where it is clear that information in indictment "not relevant, and the surplusage is prejudicial or inflammatory *in nature*") (emphasis added).

Accordingly, based on the legal standards articulated above, Panchal has not met his burden to strike Paragraph 5 of the Superseding Indictment. His motion should be denied.

IV. DEFENDANTS ARE NOT ENTITLED TO GRAND JURY INSTRUCTIONS

The defendants have filed a motion to compel the government to produce the legal instructions provided to the grand jury pertaining to Count One of the Superseding Indictment, which charges conspiracy in violation of 18 U.S.C. § 371. The charge is not, as the defendants contend, "highly complex" or "confusing." The count charges the defendants with participating in a single conspiracy with three objectives: (1) to impede, impair, and defeat the lawful functions of the FDA; (2) to introduce unapproved new drugs into commerce with the intent to defraud and mislead; and (3) to make false statements to the FDA. The defendants' core hypothesis appears to be that because the conspiracy charge is so intricate, they lack "confidence that the grand jury was properly instructed," and therefore overriding grand jury secrecy is "necessary to assess whether grand jurors were properly instructed." ECF 105 at 10. If so, the

defendants further speculate, perchance the legal instructions "would provide an independent basis for dismissal of the Indictment." *Id.*[28] This is nothing but rank speculation.

The defendants entirely fail to carry their heavy burden of establishing a compelling necessity or particularized need for these materials that would justify riding roughshod over a principal that has existed in our jurisprudence since the 17th century and that is critical to the proper functioning of the grand jury system. *See Douglas Oil Co. of California v. Petrol Stops Northwest*, 441 U.S. 211, 218 & n.9 (1979). Worse than merely failing to meet that high bar, the defendants seek to engage in precisely the type of improper fishing expedition that courts have expressly prohibited. *See, e.g.*, *United States v. Fields,* No. 15-129, 2016 WL 1428113, at *11 (E.D. Pa. Apr. 12, 2016) ("[Rule 6(e)(3)(E)(ii)] is not an invitation to engage in a fishing expedition to search for grand jury wrongdoing and abuse" (quoting *United States v. Loc Tien Nguyen*, 314 F. Supp. 2d 612, 616 (E.D. Va. 2004)); *United States v. Slade*, No. 12-0367, 2013 WL 3344341, at *4 (E.D. Pa. July 3, 2013) ("Grand jury materials may not be disclosed to the defendant 'for the purpose of a fishing expedition or to satisfy an unsupported hope of revelation of useful information.'" (quoting *United Kingdom v. United States*, 238 F.3d 1312, 1321 (11th Cir. 2001))).[29]

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[28] The defendants also argue that disclosure of the legal instructions is necessary because they claim the Superseding Indictment "do[es] not state an offense." ECF 105 at 9. As the defendants note, this argument merely reprises their motion to dismiss argument. Of course, there would be no reason to disclose the grand jury instructions if their motion to dismiss the count on that ground prevails.

[29] That the defendants are engaged in no more than an improper fishing expedition is further demonstrated by the fact that the defendants cannot possibly know whether legal instructions even exist because "under federal law the prosecutor is not obligated to provide legal instruction to the grand jury." *United States v. Lopez-Lopez*, 282 F.3d 1, 9 (1st Cir. 2002); *see also United States v. Zangger*, 848 F.2d 923, 925 (8th Cir. 1988). *Accord United States v. Segura*, No. 14-286, 2016 WL 1623182, at *4 (W.D. Pa. Apr. 25, 2016) ("Further, courts encountering a defendant claiming that he was prejudiced by alleged erroneous legal instructions

The defendants purport to bring their request for the grand jury material under Federal Rule of Criminal Procedure 6(e)(3)(E)(ii), which permits disclosure of grand jury proceedings "at the request of a defendant who shows that a ground may exist to dismiss the indictment because of a matter that has occurred before the grand jury." The Supreme Court has "consistently construed the Rule . . . to require a strong showing of particularized need for grand jury materials before any disclosure will be permitted." *United States v. Sells Engineering, Inc.*, 463 U.S. 418, 443 (1983). The Third Circuit has repeatedly applied this standard. *See, e.g.*, *United States v. McDowell*, 888 F.2d 285, 289 (3d Cir. 1989) (holding that to obtain grand jury materials, a party must show "a particularized need for that information which outweighs the public interest in secrecy"); *United States v. Weingold*, 69 Fed. App'x 575, 578–59 (3d Cir. 2003). Before a court even contemplates ordering disclosure, a defendant "must at least present some colorable, tailored reason for concern about the integrity of the process." *United States v. Houser*, No. 08-759, 2009 WL 323103, at *1–2 (E.D. Pa. Feb. 9, 2009) (citations omitted). Importantly, the issues of narrow tailoring and need balancing are reached only once a defendant meets this "heavy burden."

This is because of the robust public policy that "grand jury proceedings generally must remain secret except where there is a compelling necessity." *McDowell*, 888 F.2d at 289. Furthermore, it has long been established that grand jury proceedings carry a "strong presumption of regularity" that cannot be overcome with mere conjecture. *United States v. Bunty*, 617 F. Supp. 2d 359, 372 (E.D. Pa. 2008); *see also Hamling v. United States*, 418 U.S. 87, 139 n.23 (1974); *United States v. Calandra*, 414 U.S. 338, 345 (1974); *In re Grand Jury*

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provided by the prosecutor to a grand jury have rejected the argument, finding that *prosecutors are not even obligated to provide legal instructions to the grand jury*." (emphasis in original)).

Proceedings, 632 F.2d 1033, 1041 (3d Cir. 1980). The presumption extends to any legal instructions that might have been provided to the grand jury. *See United States v. Chalker*, No. 12-0377, 2013 WL 4547754, at *6 n.7 (E.D. Pa. Aug. 27, 2013) ("Legal instructions provided to the grand jury are entitled to the 'presumption of regularity' and can only be disclosed upon a showing of particularized need.").

In determining whether a defendant fits within the narrow exception provided by the rule, "courts generally reject unsupported beliefs and conjectures as grounds for disclosure of grand jury materials to defendants." *United States v. Shane*, 584 F. Supp. 364, 367 (E.D. Pa. 1984). Even where, as here, the defendant seeks *in camera* review, the same standard applies. *See Bunty*, 617 F. Supp. 2d at 372 ("[C]ourts should not conduct an extended *in camera* review of such materials on the basis of unsupported pleadings."); *Shane*, 584 F. Supp. at 367 (*in camera* review denied where motion based on "mere unsupported pleadings"); *Chalker*, 2013 WL 4547754, at *8 ("Since we have concluded that Defendant has failed to establish a particularized need for disclosure, an *in camera* review of the grand jury transcripts is unnecessary.").

The defendants here come nowhere close to meeting their "heavy burden." They merely speculate: "It is *possible,* for example, that . . . no group of twelve grand jurors concurred that there was a single agreement" with multiple objectives. ECF 105 at 10 (emphasis added). The defendants offer nothing to suggest their offered hypothetical has any basis in reality; rather, they rely precisely on the type of unsupported conjecture that the caselaw expressly prohibits.

Similarly, the defendants theorize that it is "unlikely" that the grand jury was properly instructed merely because the conspiracy count alleges a single agreement to violate both prongs of section 371. ECF 105 at 9-10. In so doing, the defendants mischaracterize the conspiracy charge as alleging "two distinct schemes." *Id.* However, a plain reading of the charging

language in the Superseding Indictment reveals that, in fact, the defendants are charged with entering into a single agreement to accomplish three unlawful objects: one under the "defraud" prong of section 371, and two under the "offense" prong. There is nothing unusual or particularly difficult to comprehend about such a charge, and indictments frequently charge both prongs as a single offense in a single count. *See United States v. Rigas*, 605 F.3d 194, 209–10 (3d Cir. 2010) ("what § 371 criminalizes is the unlawful agreement . . . however diverse the objects of a § 371 conspiracy may be, the emphasis remains on—and the statute is aimed at—criminalizing the illegal agreement" and noting that other circuits have "held that single counts alleging violations of both the 'offense' and 'defraud' prong of § 371 are not duplicitous."); *United States v. Hauk*, 980 F.2d 611, 615 (10th Cir. 1992) (holding single conspiracy count that charges both § 371 prongs charges "a single offense but specif[ies] alternative means to commit the offense"); *United States v. Arch Trading Co.*, 987 F.2d 1087, 1092 (4th Cir. 1987) (observing that courts permit both prongs of § 371 to be charged in a single count and listing cases). The defendants were charged with conspiracy in a perfectly conventional fashion that certainly does not qualify as particularized need to invade grand jury secrecy in order to "assess whether grand jurors were properly instructed." ECF 105 at 10.

The defendants rely heavily on an unpublished decision from this district, *United States v. Islam*, No. 20-CR-00045, 2021 WL 312681 (E.D. Pa. Jan. 29, 2021), for the proposition that they ought to be entitled to review the grand jury instructions. The case, however, is inapposite. The result in that case hinged almost entirely on the peculiarities of the charges there. It was crucial for the court that the law, regarding honest services fraud, had "changed substantially in recent years" and "remains in flux." *Id.* at *1. Moreover, the precise conduct of the *Islam* defendants was "the type of activity that has been carefully scrutinized by the courts in

determining the scope of criminal liability" and there was language in the indictment that specifically alluded to a disallowed theory of liability. *Id.* at *2. None of the peculiar issues that led the *Islam* court to review the instructions *in camera* are present here.

In the end, the defendants' motion is nothing more than an unsupported request to embark upon an unwarranted fishing expedition in derogation of centuries-old policy and caselaw. The Court should deny the motion.

V. THE GOVERNMENT WILL PRODUCE *GIGLIO* AND JENCKS MATERIAL, AS WELL AS APPROPRIATE NOTICE OF INTENTION TO INTRODUCE EVIDENCE UNDER RULE 404(b)

The government has acknowledged its duty to provide *Brady*, *Giglio*, and Jencks materials in its initial discovery letter. Moreover, the government has already produced much of the Jencks material at issue in this case. The government continues to be mindful of this duty, and has supplemented, and will continue to supplement, its discovery as appropriate.

The government will provide notice of its intention to introduce evidence pursuant to Rule 404(b) at the time of filing the government's trial memorandum, or such other time as set forth by this Court.

VI. THE GOVERNMENT HAS PRESERVED THE AGENTS' ROUGH NOTES AND *IN CAMERA* REVIEW IS NOT WARRANTED

The defendants ask this Court to order the preservation and production of agents' rough notes. ECF 98. Such an order to preserve is unnecessary as, consistent with legal requirements, the agents' notes in this case have been preserved. Regarding production, the defendants' motion should be denied as they have not met their burden to compel the government's production of agent rough notes.

Agent rough notes are subject to production only if they constitute statements falling under the Jencks Act or contain *Brady* material. *United States v. Ramos*, 27 F.3d 65, 68-70 (3d

Cir. 1994).[30] In *Ramos*, the Third Circuit reaffirmed its prior directive that the government preserve all notes of interviews with witnesses in criminal cases.[31] However, it explained that this rule exists only to permit prosecutors and then, if necessary, trial judges to review the notes to assure that no Jencks or *Brady* material is present in the notes. *Id.* If no such material exists in the notes, the notes are not produced to the defense.[32] Indeed, it is the rare case in which interview notes amount to a Jencks statement. The Jencks Act states a very limited and exclusive definition of the class of "statements" that must be produced, that are as follows:

> (1) a written statement made by said witness and signed or otherwise adopted or approved by him;
> (2) a stenographic, mechanical, electrical, or other recording, or a transcription thereof, which is a substantially verbatim recital of an oral statement made by said witnesses and recorded contemporaneously with the making of such an oral statement, or
> (3) a statement, however taken or recorded, or a transcription thereof, if any, made by said witness to a grand jury.

18 U.S.C. § 3500(e). None of those definitions fit the handwritten notes requested by the defendants.

The purpose of the Jencks Act was to limit defense access to government materials. "The Act's major concern is with limiting and regulating defense access to government papers, and it is designed to deny such access to those statements which do not satisfy the requirements of [§

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[30] The rough notes, which were used as aids to memory by the agents in preparing the typewritten reports which provide a summary of the interviewees' account, do not contain *Brady* material not included in the typewritten reports provided to defense counsel. Moreover, the Jencks Act (18 U.S.C. § 3500) compels production of grand jury transcripts, along with any other witness "statements," as defined in the Act, after the witness has testified at trial. *United States v. Hill*, 976 132, 139 (3d Cir. 1992).

[31] Consistent with applicable law, the agents' notes have been preserved. *See United States v. Vella*, 562 F.2d 275 (3d Cir. 1977).

[32] The government will make agent rough notes available to this Court to review if it wishes.

3500](e), or do not relate to the subject matter of the witness' testimony." *Palermo v. United States*, 360 U.S. 343, 354 (1959). The key limitation is that only statements that represent the witness' own words, either because they were written or adopted by him, or because they are "substantially verbatim" transcripts, are to be produced. "[I]t was felt to be grossly unfair to allow the defense to use statements to impeach a witness which could not fairly be seen to be the witness' own rather than the product of the investigator's selections, interpretations, and interpolations." *Id.* at 350; *see also Goldberg v. United States*, 425 U.S. 94, 127-28 (1976) (Powell, J., concurring) (because trial testimony rarely conforms precisely to what a witness has said earlier, it is unfair to question the witness regarding any earlier statement that is not unquestionably his).

Thus, interview notes—even those later recorded in typewritten format—rarely qualify as Jencks statements. To fall under subsection (e)(1), they must be adopted by the witness. The requirement of adoption demands that the witness sign or otherwise formally approve the statement. *Gov't of Virgin Islands v. Lovell*, 410 F.2d 307, 310 (3d Cir. 1969). "This requirement clearly is not met when the lawyer [or agent] does not read back, or the witness does not read, what the lawyer [or agent] has written." *Goldberg*, 425 U.S. at 110 n.19. *Accord United States v. Wolfson*, 302 F. Supp. 798, 817 (D. Del. 1971), *aff'd*, 454 F.2d 60 (3d Cir. 1972); *United States v. Newman*, 849 F.2d 156, 160 (5th Cir. 1988); *United States v. Pisello*, 877 F.2d 762, 768 (9th Cir. 1989).

In this case, the typed reports of interview were not approved or adopted by the witnesses and were never signed by them. Interview notes also hardly ever qualify as "substantially verbatim" statements under subsection (e)(2). "Typical interview notes are selective—even episodic—and therefore fall outside of subsection (e)(2)." *Goldberg*, 425 U.S. at 126 (Powell, J.,

concurring). Even where brief, precise quotations are included, that is "inadequate to qualify the notes as *Jencks* material." *United States v. Gross*, 961 F.2d 1097, 1105 (3d Cir. 1992).

In fact, using this standard, even the typed notes already provided are not properly Jencks material, but in the interest of over-disclosure, the government has already provided many typed reports of witnesses to the defendants.[33]

Finally, the defendants are required to make a *prima facie* showing of the existence of a "witness statement" as defined above that has not been disclosed, to require the court to review the statement *in camera* to determine if its production is mandated. *United States v. Smith*, 984 F.2d 1084, 1086 (10th Cir. 1993); *see also United States v. Sanchez-Gonzales*, 294 F.3d 563, 568 (3d Cir. 2002) (citing *Smith* favorably). As a threshold matter, the defendants have not met their burden to warrant a request for the Court to conduct an *in camera* review of agents' handwritten notes. Accordingly, their motion should be denied.

[33] While it is the practice of the United States Attorney's Office in this district to produce such reports (known as FBI 302's, and the like) to the defense before trial, it must be recognized that this practice also is not required by law. Courts have held unanimously that interview reports such as those prepared here are not Jencks material. *See, e.g.*, *United States v. Allegrucci*, 299 F.2d 811, 813 (3d Cir. 1962); *United States v. Starusko*, 729 F.2d 256, 263 (3d Cir. 1984); *United States v. Foley*, 871 F.2d 235, 238-39 (1st Cir. 1989) (FBI 302's were not Jencks statements, where they plainly were not substantially verbatim; it is irrelevant that the agent was a "punctilious" note taker who often asked the witness to slow down, and read portions back to the witness to assure that the notes were correct); *United States v. Ricks*, 817 F.2d 692, 697-98 (11th Cir. 1987); *United States v. Paden*, 787 F.2d 1071, 1077-78 (6th Cir.1986); *United States v. Claiborne*, 765 F.2d 784, 801 (9th Cir. 1985); *United States v. Edwards*, 702 F.2d 529, 531 (5th Cir. 1983).

CONCLUSION

For these reasons, the government respectfully submits that the defendants' motions should be denied in their entirety, without a hearing.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that the foregoing United States' Omnibus Response to Defendants' Pretrial Motions was served on all counsel of record by email and ECF filing.

Dated: December 22, 2021

/s/ Patrick J. Murray
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